

Effect of Surgical Safety Checklist Implementation on the Occurrence of Postoperative Complications in Orthopedic Patients

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ABSTRACT: **Background:** Surgical adverse events are errors that emerge during perioperative patient care. The World Health Organization recently published “Guidelines for Safe Surgery.”

Objectives: To estimate the effect of implementation of a safety checklist in an orthopedic surgical department.

Methods: We conducted a single-center cross-sectional study to compare the incidence of complications prior to and following implementation of the Guidelines for Safe Surgery checklist. The medical records of all consecutive adult patients admitted to the orthopedics department at Wolfson Medical Center during the period 1 July 2008 to 1 January 2009 (control group) and from 1 January 2009 to 1 July 2009 (study group) were reviewed. The occurrences of all complications were compared between the two groups.

Results: The records of 760 patients (380 in each group) hospitalized during this 12 month period were analyzed. Postoperative fever occurred in 5.3% vs. 10.6% of patients with and without the checklist respectively ($P = 0.008$). Significantly more patients received only postoperative prophylactic antibiotics rather than both pre- and postoperative antibiotic treatment prior to implementation of the checklist (3.2% vs. 0%, $P = 0.004$). In addition, a statistically non-significant 34% decrease in the rate of surgical wound infection was also detected in the checklist group. In a logistic regression model of postoperative fever, the checklist emerged as a significant independent predictor of this outcome: odds ratio 0.53, 95% confidence interval 0.29–0.96, $P = 0.037$.

Conclusion: A significant reduction in postoperative fever after the implementation of the surgical safety checklist occurred. It is possible that the improved usage of preoperative prophylactic antibiotics may explain the reduction in postoperative fever.

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KEY WORDS: checklist, safe surgery, complications, postoperative fever, wound infection

Surgical adverse events are errors arising during perioperative patient care that endanger the patient and might be life-threatening. While not all surgical complications are preventable, all preventable adverse events are, by definition, caused by error [1]. The adverse event rate in hospitalized patients has consistently been reported to be 3%–4% [2–4]; however, among patients admitted for surgery the rate is considerably higher – more than 21% [5]. It has been estimated that approximately half of these adverse events are attributable to error and are therefore preventable [1,5–7]. Often cited as contributing to preventable surgical adverse events are system failures due to both human and organizational factors [8,9], problems in communication [10], and inadequate team skills [11].

Surgical care can be improved through implementation of evidence-based practice recommendations. To that end, the World Health Organization recently published “Guidelines for Safe Surgery” [1], which included a 24-item checklist of practices to ensure the safety of surgical patients. These guidelines were designed to be modifiable according to the local needs of a given surgical unit. Using a 19-item WHO-based safety checklist, Haynes et al. [12] documented a 36.3% relative reduction in total adverse events including death, and a 46.7% relative reduction in in-hospital mortality, in a multinational patient cohort admitted for non-cardiac surgery. A surgical safety checklist was recently adopted as a standard of care by the Israel Ministry of Health [13].

Hospitalization for orthopedic surgery represents an estimated 6.3% of all hospital admissions and 10.2% of all in-hospital procedures [14]. Preventable surgical adverse events include surgical site infection [15], venous thromboembolism [16], and anesthesia errors [17].

The present study was designed to evaluate the effect of implementing a set of surgical safety guidelines on postoperative fever. It was hypothesized that timely administration of prophylactic antibiotics, during the checklist process, might decrease the incidence of this endpoint.

PATIENTS AND METHODS

Approval for the study was obtained from the institutional ethics committee. This single-center cross-sectional study was designed to compare the incidence of postoperative fever defined as orally measured body temperature $> 38^{\circ}\text{C}$ prior to and following implementation of the modified WHO Guidelines for Safe Surgery checklist among patients admitted for orthopedic procedures.

Additionally, a composite postoperative complications endpoint was measured and defined as the first occurrence of surgical wound infection, surgical wound disruption, acute renal failure, bleeding requiring transfusion of four or more units of red cells within the first 72 hours post-surgery, cardiac arrest, unconsciousness of ≥ 24 hours duration, venous thromboembolism, myocardial infarction, unplanned tracheal intubation, sepsis, septic shock, systemic inflammatory response syndrome, mechanical ventilation for ≥ 48 hours, pneumonia, pulmonary embolism, stroke, or unplanned return to the operating room. This composite endpoint was also compared prior to vs. after implementation of the checklist.

COHORT SELECTION

We reviewed the medical records of all consecutive adult patients admitted to the orthopedics department at Wolfson Medical Center from 1 July 2008 to 1 January 2009 inclusive (pre-checklist “control group”) and from 1 January 2009 to 1 July 2009 (post-checklist “study group”) in the period immediately following its implementation). Data were extracted from medical records using standardized data sheets completed by a single data collector.

STUDY INTERVENTION

A modified WHO-based surgical safety checklist used at Wolfson Medical Center was employed starting 1 January 2009 [see Appendix]. In addition to items such as verification of the patient’s identity and site of surgery, this checklist includes steps to ascertain that prophylactic antibiotics are administered at the correct time (30–60 minutes) before surgery.

Data were extracted from patients’ medical records by a single investigator using a standardized query form. This information included patients’ demographic characteristics, intraoperative data including type of anesthesia, length of hospitalization, and postoperative data.

STUDY ENDPOINTS

The primary endpoint of the present study was the first occurrence of postoperative fever, defined as orally measured body temperature $> 38^{\circ}\text{C}$. This endpoint was compared prior to vs. after implementation of the surgical safety checklist.

STATISTICAL ANALYSIS

With a sample size of 760 subjects ($n=380$ per group), the present study was designed to have 80% power to detect a true, relative, by-intervention (checklist implementation) difference in the postoperative fever rate of 54%, from 11% before surgery to 5% after implementation of the surgical safety checklist. This calculation uses the two-sided Fisher’s exact sample size estimate for independent groups with a continuity-corrected chi-square test.

Data were analyzed using SPSS statistical analysis software version 21.0 (IBM Inc., USA). Continuous data were described as mean \pm standard deviation while categorical data were described using frequency counts and are presented as $n(\%)$. The primary endpoint, postoperative fever, was modeled using logistic regression including intervention status (checklist yes/no) as a predictor variable in all models. Included in this model was a variable representing patient mix, developed using analysis of principal components and including comorbidities identified as differing between groups: hypertension, chronic obstructive pulmonary disease, collagen disease, “other” diseases (i.e., prior, intercurrent, healed medical conditions such as pneumonia, prior surgeries, etc.), and steroid therapy. Additionally, the composite non-orthopedic surgical complication endpoint was modeled using logistic regression analysis. Adherence to the surgical safety checklist was ascertained in the post-checklist group.

RESULTS

The records of 760 patients (380 in each group) hospitalized during the 12 month period (6 months before and 6 months after implementation of the checklist) were analyzed. Descriptive data are presented in Tables 1–3.

As shown in Table 1, patients undergoing surgery prior to implementation of the checklist differed from those with post-checklist implementation. Specifically, the pre-checklist group had significantly more hypertension, collagen disease, “other” disease, chronic prescribed medications and steroids, and significantly less COPD than the post-checklist implementation group.

Table 2 indicates that compared to subjects undergoing surgery post-checklist implementation, individuals undergoing surgery prior to checklist implementation had significantly more lower limb and urgent surgeries, and their surgeries were performed more frequently by residents than by senior attending physicians.

Type of anesthesia did not differ by checklist; specifically, 52.1% of checklist subjects vs. 47.9% of pre-checklist subjects underwent general anesthesia ($P = 0.2$). The remaining subjects in both groups had spinal anesthesia.

COPD = chronic obstructive pulmonary disease

Table 1. Demographic data

Variable	Without checklist	With checklist	P value
Age (yr)	66 ± 20	64 ± 21	0.155
Length of hospital stay (days)	7.3 ± 6	7.4 ± 9	0.132
Females (%)	59.4	58.1	0.712
ASA class (% of patients)*			< 0.0001
ASA I	22.6	34.3	
ASA II	63.4	45.7	
ASA III	13.9	20	
ASA I + II vs. ASA III + IV (%)	16.4	20.8	0.192
Diabetes mellitus (%)	20.1	22.1	0.508
Obesity (%)	6.9	7.5	0.754
Chronic renal failure (%)	8.7	7.7	0.611
Chronic liver disease (%)	1.3	2.4	0.276
History of congestive heart failure (%)	16.7	17.3	0.820
Ischemic heart disease (%)	20.1	18.4	0.541
Hypertension (%)	56.3	41.1	0.0001
Chronic obstructive pulmonary disease	5.3	9.8	0.018
Collagen disease (%)	2.9	0.8	0.032
Immune disease (%)	0	2.7	0.01
Other comorbidities (%)**	63	55.9	0.048
Allergy including to drugs (%)	23.5	21.3	0.445
Chronic medication (%)	77.2	66.8	0.002
Steroid treatment (%)	2.9	0.5	0.012

Results are expressed as mean ± SD or percentage

*American Society of Anesthesiologists class

**Previous, intercurrent, healed medical conditions such as pneumonia, prior surgeries, etc.

Table 2. Surgery characteristics

	Without checklist	With checklist	P value
Duration of surgery (min)	80 ± 39	82 ± 44	0.625
Urgency of surgery (%)			0.005
Elective	21.7	30.8	
Urgent	78.3	69.2	
Bilateral surgery (%)	0.3	0.8	0.315
Site of surgery (%)			< 0.0001
Upper limb	12.2	27.9	
Lower limb	87.8	68.7	
Spine	0	3.4	
Use of tourniquet (%)	35.7	36.3	0.858
Surgery in which attending surgeon was present (%)	68.3	65.2	0.367
Surgery performed by resident (%)	93.4	82.4	< 0.0001
Estimated intraoperative blood loss > 500 ml (%)	0.5	0.8	0.686
Other surgical complications (%)	0.8	1.6	0.339

Table 3. Use of antibiotics, fever and infection, other post-surgical complications and death

	Without checklist	With checklist	P value
Use of prophylactic antibiotics (%)	97.4	97.9	0.641
Antibiotics administered only postoperatively (%)	3.2	0	0.004
Type of antibiotic: IV cephalosporin (%)	89.7	92.3	0.456
Antibiotic dose repeated (%)	84.4	80.9	0.200
Postoperative fever (%)	10.6	5.3	0.008
Postoperative leukocytosis (%)	1.1	2.1	0.241
Surgical wound infection (%)	3.2	2.1	0.368
SIRS (%)	0.5	0.3	0.564
Septic shock (%)	0	0.3	0.316
Infectious pathogen identified (%)	1.6	0.8	0.505
Wound infection not healed before discharge from the hospital (%)	0.3	2.4	0.011
Prosthesis removed due to infection (%)	0.5	1.3	0.286
Composite postoperative complications (%)	25.9	18.9	0.02
Postoperative cognitive dysfunction (%)	2.1	1.3	0.401
Mortality (%)	0.8	2.7	0.049

Results are expressed as percentage

SIRS = systemic inflammatory response syndrome

Table 3 presents the characteristics of postoperative outcomes. Significantly more subjects undergoing surgery prior to checklist implementation had postoperative fever. These patients also had more composite postoperative complications and received antibiotic therapy only postoperatively. Postoperative fever did not differ by the mode of anesthesia used: 8.2% of subjects with general anesthesia and 6.9% of patients with spinal anesthesia had postoperative fever ($P = 0.6$). A non-significant 34% relative decrease in surgical wound infection rate was also detected in the checklist group. On the other hand, subjects in the pre-checklist group had a higher rate of healed wound infection at discharge and a lower mortality rate than individuals undergoing surgery post-checklist implementation.

In the checklist group, there were seven in-hospital deaths. Three died from sepsis (pancreatitis, pneumonia and urosepsis, respectively), two from acute myocardial infarction, one from acute chronic renal failure, and one from pulmonary embolism. In the group prior to checklist implementation there were two deaths (one due to myocardial infarction and one to aspiration pneumonia). Wound infection did not differ by type of anesthesia: 2.2% of subjects with general vs. 4.3% of subjects with spinal had wound infection ($P = 0.2$).

LOGISTIC REGRESSION ANALYSIS

In a model of postoperative fever [Table 4], the checklist emerged as a significant independent predictor of this outcome:

Table 4. Logistic regression model of postoperative fever

	Odds ratio	95%CI*	P value
Checklist (yes)	0.53	0.29–0.96	0.037
Age (yr)	1.02	0.99–1.42	0.0778
Gender (male)	1.39	0.77–2.51	0.269
Urgency (urgent)*	1.08	0.53–2.19	0.84
Patient mix**	0.93	0.68–1.28	0.66
Surgery duration (min)	1.01	1.007–1.02	< 0.0001
Attending physician***	1.05	0.54–2.03	0.88
Hip surgery	2.72	1.17–6.28	0.02

*Urgency indicates urgent vs. elective procedure

**Patient mix includes terms for hypertension, chronic obstructive pulmonary disease, “other” comorbidities (i.e., prior, intercurrent, healed medical conditions such as pneumonia, prior surgeries, etc.) and steroid therapy

***Attending physician indicates surgery performed by senior physician vs. resident

The model is significant ($P < 0.0001$) and correctly classifies 91% of study participants

odds ratio 0.53, 95% confidence interval 0.29–0.96 ($P = 0.037$), even after controlling for age, gender, procedure duration, urgency, location (hip vs. others), whether the surgeon was the attending or other, and patient mix, indicating that patients with checklist had a relative reduction of 47% in odds of this outcome. Duration of procedure increased the odds of this outcome: OR 1.013, 95%CI 1.007–1.019 ($P < 0.0001$), meaning that each 1 minute increase in procedure duration increased the odds of postoperative fever by a relative 1.3%. Location of procedure (hip vs. other locations) also increased the odds of postoperative fever: OR 2.72, 95%CI 1.17–6.28 ($P = 0.02$), such that patients undergoing this procedure were 2.7 times more likely to have this outcome than others. Other variables in the equation – namely gender, urgency, attending physician as surgeon vs. resident, and patient mix – did not significantly predict this outcome. The model was significant ($P < 0.0001$) and correctly classified 91.7% of subjects with this outcome.

Though the composite postoperative complication endpoint was significantly lower after implementation of the checklist in the univariate analysis, the checklist did not emerge as a significant predictor in the logistic regression analysis of this endpoint. Age was associated with a relative 53% increase in risk of this outcome (OR 1.047, 95%CI 1.031–1.064, $P < 0.0001$). Duration of surgery also predicted this outcome (OR 1.007, 95%CI 1.002–1.012, $P = 0.004$), such that each 1 minute increase in surgical duration increased the odds of this outcome by 0.07%. Hip surgery also increased risk of this outcome (OR 2.27, 95%CI 1.27–3.76, $P = 0.001$), meaning that this procedure (relative to others) more than doubled the risk of this endpoint. Gender, urgency of procedure and, as previously noted, checklist implementation

OR = odds ratio

CI = confidence interval

did not predict this outcome. The model was significant ($P < 0.0001$) and correctly classified 77.3% of study participants.

DISCUSSION

Around the world approximately 234,000,000 surgical procedures per year are performed, a volume far outnumbering such important health issues as childbirth and incident or prevalent cases of human immunodeficiency virus [18]. Of all patients undergoing surgery, 1 million will die and another 7 million will sustain disabling complications. It has thus been proposed that in view of the high death and complication rates of surgical procedures, surgical safety should be a substantial global public health concern [18].

The WHO checklist [1] proposes solutions to problems such as wrong-site surgery by marking the surgical site [19]. It is noteworthy that before implementation of the checklist there were 1500–2500 wrong-site surgery incidents every year in the U.S. [20]. To date, it has not been conclusively demonstrated that the WHO checklist has succeeded in decreasing the incidence of wrong-site surgery.

In the early 2000s, unsuccessful use of surgical safety checklists was reported in some U.S. hospitals, probably attributable to incomplete or improper use of the method [21]. This was met with a call for adoption of the more comprehensive WHO checklist. Proper implementation of a surgical safety checklist in non-cardiac surgeries has been associated with a significant decrease in the overall inpatient complication rate from 11.0% at baseline to 7.0% after introduction of the checklist ($P < 0.001$) [12].

In addition to preventing wrong-patient/wrong-site surgeries, the WHO checklist ensures the performance of basic safety and therapeutic measures prior to the anesthesia and surgery. Of these, the timely administration of prophylactic antibiotics is of utmost importance as surgical site infection is considered a preventable complication of surgery, including orthopedic surgery [16].

In our study in orthopedic patients, postoperative fever declined from 10.3% at baseline to 5.3% after introduction of the checklist ($P = 0.008$). This difference was preserved in the logistic regression model even after correcting for a number of potential confounders including age, gender, surgical site location, procedure urgency, physician performing the procedure, and patient mix. This difference may be at least partially attributable to the significant decline in the proportion of patients receiving only postoperative antibiotic prophylaxis in the checklist group, from 3.2% to 0% ($P = 0.004$). Additionally, a statistically non-significant 34% reduction in wound-site infection was also observed in patients undergoing surgery post-checklist implementation. The type of anesthesia (general vs. regional) was not associated with the propensity to develop postoperative fever.

However, checklist implementation has not been uniformly associated with significant reductions in adverse events and outcomes. In our study, checklist implementation was not associated with a decrease in the composite postoperative complications endpoint after controlling for confounding variables; moreover, mortality was significantly higher in the checklist group. While reasons for mortality did not appear to be associated with checklist implementation, the increased mortality cannot be ignored. Implementation of surgical safety checklists has not always been accompanied by a reduction of early complication and mortality rates in patients undergoing orthopedic surgery [22]. Conversely, the proportion of general and vascular surgery patients who received antibiotics only after the surgical incision has decreased, while compliance with prophylactic antibiotic administration timing has increased after checklist implementation [23].

According to the WHO checklist recommendations [1,12], confirmation of prophylactic antibiotic administration \leq 60 minutes before incision is performed during performance of the surgical safety checklist, prior to skin incision. With our modified checklist, the administration of antibiotics was confirmed earlier, i.e., immediately after the end of the sign-in period.

Our study is limited by its cross-sectional design where exposure and outcome are simultaneously measured, precluding determination of causality. A clinical trial could have assigned causality to checklist implementation; however, it would not have met ethical requirements. Another limitation is obtaining “control” medical records from the year prior to that of the “study” records. Clearly this increases the risk of selection bias. An attempt was made to control for this by including terms for patient mix and surgeon in the regression analyses. While this method provides some assurances, it cannot rule out that findings are in fact “stand-ins” for other associations not considered by the investigators. Controlling for potentially confounding variables revealed that checklist implementation was a significant independent predictor of decreased postoperative fever. Nevertheless, the finding is an association, and as noted, causality cannot be assigned.

In conclusion, this cross-sectional cohort study of orthopedic surgical patients found a significant reduction in postoperative fever after implementation of the surgical safety checklist. The role of the checklist in reducing the postoperative fever rate persisted after controlling for potential confounders, including patient age and gender, procedure urgency, physician performing the procedure, procedure duration, and patient mix. The reduction in the proportion of patients receiving antibiotic prophylaxis only postoperatively may also explain this observation.

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Appendix. Surgical Safety Checklist used at Wolfson Medical Center

Sign out – at the end of surgery	Time out – before skin cut	Sign in – before surgery
<ul style="list-style-type: none"> • Surgical instruments' counting confirmed & recorded by the nurse • Pathology samples sent if applicable • Damaged equipment sent for repair if applicable 	<ul style="list-style-type: none"> • Equipment sterility checked with indicators confirmed by the nurse • Prophylactic antibiotics administration reconfirmed 	Tick or write wherever correct <ul style="list-style-type: none"> • Identity simultaneously confirmed from patient, chart & identification band • Surgical site • Procedure • Simultaneously all team members check surgical site • Informed consent for surgery & anesthesia • History of allergy yes/no • Any prosthesis? yes/no • Surgical table & anesthesia & surgical equipment checked & ready
<ul style="list-style-type: none"> • 		<ul style="list-style-type: none"> • Drugs ready • Type of anesthesia: general, regional, local, sedation • Prophylactic antibiotics started if applicable • Imaging & results available • Risk of aspiration & difficult airway yes/no • Blood available if applicable • Contagious disease yes/no
Signatures Surgeon Anesthesiologist Nurse	Signatures Anesthesiologist Nurse	Signatures Surgeon Anesthesiologist Nurse