

EFFECT OF CHECKLIST ON THE OCCURRENCE OF POSTOPERATIVE COMPLICATION ON SURGICAL PATIENT

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ABSTRACT

Background: Surgical safety checklists (SSCs) are designed to improve interprofessional communications and ultimately avoiding catastrophic errors that often characterizes the culture of surgical teams. However, data on the effect of surgical checklists implementation are scarce in the study area. The purpose of this research project was to directly examine the effect of utilization surgical safety checklist on patient outcomes at the University of Gondar Hospital, in Northwest Ethiopia. **Material and methods:** Institution based cross-sectional study was conducted at University of Gondar Hospital from January to May 2013. We reviewed medical records of all consecutive patients admitted to the surgery department (N=403). For those who have clinical symptoms of surgical site infection, a laboratory diagnosis was performed to compare occurrences of all postoperative complication among patients with and without utilization of surgical safety checklist. **Results:** During the study period from 403 patients operated, SSCs were attached for only 158 (39.2%) of the surgical patients. The postoperative complication was observed in 238 (59 %) of the patients, and postoperative fever was the primary complication accounting for 70 (17.3%) of all the complication. Surgical wound infection and pneumonia accounted for 47(16.6%) and 33(11.7%) respectively. *S. aureus* was the predominantly isolated bacteria accounted for 7(30%). Also, a statistically non-significant 11.2% decline the rate of surgical wound infection in the checklist group. In a logistic regression model of postoperative fever, the SSCs emerged as a significant independent predictor of this outcome: (OR = 0.49, 95% CI 0.31–0.75, and P-value = 0.001). **Conclusions and recommendations:** Patients with checklist have observed significant reductions of postoperative complication particularly bacterial infection. It is possible to some extent that the improved usage of the checklist and preoperative prophylactic antibiotics may be implicated in the reduction of postoperative fever and bacterial infection.

KEYWORDS: Surgery; Safety; Observation; Implementation; Surgeons; Operating room; communication; WHO Surgical Safety Checklist

Introduction

Surgical care can be improved through implementation of evidence-based practice recommendations. To that end, the

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World Health Organization published "Guidelines for Safe Surgery" in 2009.[1] Investigators documented a significant reduction in mortality and other postoperative complications with the use of the WHO surgical safety checklist.[2]

Since then, the checklist has been adopted by more than 3,900 hospitals in 122 countries, representing more than 90% of the world's population. Twenty-five countries are moving to adopt the checklist at a national level.[3] Thus, checklists have become synonymous as best practice in high-risk areas such as surgery. Checklists hold the promise of reducing catastrophic errors such as wrong site/wrong patient surgery, improving inter-professional communications, enhancing work satisfaction and flattening the hierarchy that often characterizes the culture of surgical teams.[4]

As a strategy to improve patient safety, checklists have become commonplace in healthcare practice. Surgical checklists give emphasis to several most critical components of patient safety: safe anesthesia and airway function, correct surgical site/side, infection prevention, and effective teamwork.[4] Some published systematic review on the impacts and implementation of checklists suggests that checklist use was associated with increased detection of potential safety hazards.[5] However the results of many studies included reflect patterns of practice on a local or regional level rather than collective on a wider scale.[6]

Thus, evaluating the impact of new clinical practice initiatives on the outcomes of care is problematic in the absence of accurate, large-scale patient outcome data.[7,8] Further examination to evaluate to what extent checklists improve clinical outcomes is needed. To this end, we conducted a comparative cross-sectional study that tested the effects of surgical safety checklists on complication rates in surgical patients. To our knowledge, this is the first study in which the use and the effects of the surgical safety checklist are examined in the surgical patient. The aim of this study was to determine whether the utilization of the checklist has an impact on postoperative complications such as surgical wound infection, unplanned readmission, postoperative fever, postoperative prophylaxis and the length of hospital stay.

Materials and methods:

The study was conducted in a 500-bed university hospital serving a population of 6 million inhabitants in North West part of Ethiopia. The average number of operations per year is 6200. There are four operational departments: Obstetrics and Gynecology; General Surgery; Orthopedics and Urologic surgery. All units participated in this study.

This single-center cross-sectional study was designed to compare occurrences of all postoperative complication among 403 patients with and without utilization surgical safety checklist. This study was initiated in January 2013 by a multidisciplinary team including anesthetists' microbiologist, surgeons, nurses and a quality officer from the University of Gondar Hospital, in collaboration with the WHO patient safety foundation.

A comprehensive, structured questionnaire was designed to anesthetists, surgeons and scrub nurses in consecutive operations during a five-month period. The original checklist which is developed by WHO was translated with minor changes to set hospital operation room environment. The checklist coordinator was compelled only to tick the checkbox if an answer was given to the corresponding question. Finally, the checklist became part of the patient's paper-based notes and attached to the medical record of the patient. Clinical and demographic data were collected from medical records for all patients who

underwent general surgery and were discharged during this period. Patients who were discharged without having undergone surgery and patients with a hospital stay of fewer than 24 hours were excluded and data were extracted using standardized data sheets completed by trained data collectors.

Sample Processing and Preliminary identification:

After the operation, patients were followed by a surgeon to assess the progress of wound healing until they become discharged as part of the routine activity. From all patients whose diagnosis was confirmed as wound sepsis by a surgeon, wound discharge was aseptically obtained before the wound was cleaned with an antiseptic solution and before antibiotic therapy was started. Specimens were collected on sterile cotton swabs without contaminating them with skin commensals. Following collection, the swabs were inoculated into MacConkey agar, BAP and mannitol salt agar (Oxoid Limited).

The inoculated agar plates were incubated at 35°C for 24-48 h. Then the growth was inspected to identify the bacteria. Preliminary identification of bacteria was performed based on gram reaction, colony characteristics of the organisms like hemolysis on blood agar, changes in physical appearance in differential media and enzyme activities of the organisms.

Biochemical tests were performed on colonies from primary cultures for final identification of the isolates. Gram-negative rods were identified by performing a series of biochemical tests (Oxoid Limited). Namely, triple sugar iron agar, indole, Simon's citrate agar, lysine iron agar, urea, mannitol, and motility. Gram-positive cocci were identified based on their gram reaction, catalase and coagulase test results [23]. International control bacteria strains, *E. coli* (American Type Culture Collection [ATCC] 25922) *S. aureus* (ATCC 25923) and *P. aeruginosa* (ATCC 27853) were used in controlling the tests carried out.

Statistical analysis

Data were analyzed using SPSS statistical analysis software version 20. The distributions of the covariates were described using mean and standard deviation for continuous variable and numbers and percent for categorical variables. Statistical significance was defined as two-sided $p < 0.05$. Postoperative fever was modeled using logistic regression including intervention status (checklist yes / no) as a predictor variable in all models to compute the Relative Risk (RR) and 95%CI (confidence interval). Additionally, the composite non-major surgical complication endpoint was modeled using logistic regression analysis. Adherence to the surgical safety checklist was determined in the post-checklist group. Ethical clearance and official permission were secured to conduct the study from the ethical board of University of Gondar and medical director of the University of Gondar Hospital respectively.

Results

Demographic characteristics

During the study period, 403 study participants' were schedule, of whom 1.7% underwent more than one procedure; the total number of surgical procedures was 411. Two hundred eleven, (52.3%) were male, while the rest were female. The sex ratio of between male to female was 1:1.1. The majority (89.4%) of the study participant were greater than 17 years of age. Surgical safety checklists were attached for 158 (39.2%) operations. Most checklists were employed for patient came from the rural area,

without a co-existing disease and got prophylaxis before the operation, which accounted for 41%, 36%, and 42% of operations, respectively.

The checklists were employed most commonly in general surgery 83 (52.5%) followed by obstetrics-gynecology 61 (38.6%) and Orthopedics 14 (8.8%). Most checklists were in use on the day shift, for elective surgery, and in procedures involving general anesthesia, which accounted for 62.6%, 32.2%, and 74.6% of operations, respectively. Operation characteristics differences among patients with and without utilization of surgical safety checklist is more illustrate in (Table 2).

During the study period, 403 study participants underwent surgery. Of these, 59% (238/403) of the participants developed a post-operative complication. Among these, surgical safety checklist was attached only to 23.5% (56/158) patients. However, the complication was 74.3% (182/245) in comparison groups. Postoperative fever, surgical wound infection and pneumonia were the top three postoperative complication among patients without utilization of checklist which accounts 42.3%, 30.2%, 19.7% respectively. Postoperative complications among patients with and without use of checklist are more illustrate in (Table 3).

Logistic regression analysis

In a model of postoperative fever, the checklist becomes as a significant independent predictor of postoperative fever odds ratio 0.490, 95% confidence interval 0.317 – 0.758 (P = 0.001) even after controlling for gender, coexisting disease, urgency of surgery, time of operation and anesthesia type. Indicating that patients with checklist had a relative reduction of 51% in odds of this outcome. Having prophylaxis decreases the odds of this outcome: OR 0.424, 95%CI 0.223–0.806 (P = 0.009), such that patients with prophylaxis had a relative reduction of 58% in odds of this outcome. Other variables in the equation – namely gender, urgency, co-existing disease, time of operation did not significantly predict this outcome.

Though the composite postoperative complication endpoint was significantly lower in a patient underwent with the surgical safety checklist in the univariate analysis, in addition to the checklist urgency of surgery was a significant predictor in the logistic regression analysis of this endpoint with a relative 53% increase in risk of this outcome (OR 1.99, 95%CI 1.271–3.145, P = 0.003).

Bacterial pathogens were isolated from 36 patients showing an isolation rate of 57.1%. Mixed bacterial infection was observed. The predominant isolated pathogen was *S. aureus* 11 (30.5 %), *E.coli* 9 (25%), *CoNS* 6 (16.6%). The type and frequency of pathogens isolated from surgical site discharge are more illustrated Table 5.

Discussion

Little is known about the amount and availability of surgical care globally. Around the world, approximately 234,000,000 surgical procedures per year are performed. Of all patients undergoing surgery, 1 million will die, and another 7 million will sustain disabling complications. It has thus been proposed that given the high death and complication rates of surgical

procedures, surgical safety should be a substantial global public health concern. [9]

To our knowledge, this is the first cross-sectional study in which the use of locally modified WHO surgical safety checklist in surgery is examined. The finding of our study was that the utilization of the checklist increased safety-related performance in the operation room (OR), and a contemporary adverse event analysis showed a reduction in postoperative fever, wound complications, and unplanned readmissions. Our overall results are in agreement with the studies [10] where communication and teamwork improved, and complications significantly by using the checklist.

Surgical site infections cause a substantial risk of an unplanned readmission to the hospital. In our study, among 67 surgical site infections 5 of them were planned for readmission, and all of them were underwent surgery without surgical safety checklist. Our findings were in line with the study done in Canada [10], where the surgical site infections declined almost by half [11]. According to this study, there is a strong direct correlation between prophylactic antibiotics and surgical site infections (p = 0.042). In similarity with other studies that antibiotic prophylaxis does significantly reduce surgical site infections after major surgery [12, 13]. Overall, the surgical site infection rates in our study were similar to a study done in Canada [10]. From the total 258 surgical complications, 102 of them developed postoperative fever among this 72% of them underwent surgery without surgical safety checklist (OR= 0.447), (P = 0.005).

The types of anesthesia (general vs. spinal), urgency and gender, were not associated with the tendency to develop post-operative fever.

This difference was preserved in the logistic regression model even after correcting for some potential confounders including gender, time of the procedure, procedure urgency, anesthesia, and prophylaxis.

A total 67 suspected surgical wound infection were examined using culture in microbiology laboratory 36(53.7%) of the cases were positive for the laboratory result. Among these only 9, (39.1%) positive laboratory results surgical safety checklists were attached. 17, (47.2%) of the isolates were Gram-positive bacteria. 19 (52.8%) of the isolates were a Gram-negative rod. This finding is again in line with studies in Gondar [14], [15] and Bahir Dar [16].

This result showed that *S. aureus*, *E.colie*, and *CoNS* species were the major three bacterial pathogens associated with surgical wound infections. This result is consistent with data in Eastern Nigeria [17] and Addis Ababa 2011. The profiles of bacterial isolates from postoperative surgical site infection were *S. aureus* 11 (30%), *E. coli* 9 (25%), Coagulase negative staphylococci 6 (16.6%), *Proteus mirabilis* 2 (5.5%), *Proteus volgaris* 2 (5.5%), *Klebsiella pneumonia* 3 (8.3%), and *P. aeruginosa* 3(8.3%). This finding is again in agreement with studies in Addis Ababa and logos-Nigeria [17, 18].

Limitation of the study

This study has some limitations: It was conducted in only one setting and in a short period which comprises of the relatively small sample which may induce type II (β) error. Therefore, the results might not apply to other settings. Operation site selections are not stated as clean contaminated, and dirty that could be again a source of bias. Moreover, the study relies on data from the patients' medical records and laboratory culture result. Validation of checklist utilization is not presented. The

Table 1 Demographic data distributions of patients were undergoing elective and emergency surgery at University of Gondar Teaching Hospital from January to May 2013.

| Variable | | Checklist attached (n=158) | Checklist not attached (n=245) | P.value |
|--|--------------|-------------------------------|-----------------------------------|---------|
| Sex | Male | 90 | 121 | 0.137 |
| | Female | 68 | 124 | |
| Age(yr) | 33.11± 16.39 | 33.06 ± 17.04 | 33.05 ± 15.98 | 0.818 |
| Residence | Rulare | 91 | 129 | 0.331 |
| | Urbane | 67 | 116 | |
| Co- existing disease | Yes | 12 | 21 | 0.727 |
| | No | 146 | 224 | |
| Prophylaxis is given before operation | Yes | 142 | 190 | 0.001 |
| | No | 16 | 55 | |

Table 2 Surgery characteristics of patients who underwent for elective and emergency surgery at University of Gondar Teaching Hospital from January to May 2013.

| Variable | | the checklist is attached | checklist is not attached | Total | P.value |
|--|-------------|------------------------------|------------------------------|-------|---------|
| ASA class (% of patients)* | ASA I | 126 | 204 | 330 | 0.328 |
| | ASA II | 28 | 39 | 67 | |
| | ASA III | 4 | 2 | 6 | |
| Anesthesia type | General | 118 | 169 | 287 | 0.217 |
| | Spinal | 40 | 76 | 116 | |
| Urgency of surgery | Elective | 51 | 113 | 164 | 0.006 |
| | Emergency | 107 | 132 | 239 | |
| Time of operation done | Day** | 99 | 133 | 232 | 0.097 |
| | Night | 59 | 112 | 171 | |
| Type of surgery | Surgery*** | 83 | 175 | 258 | |
| | Gyne obs. | 61 | 42 | 103 | |
| | Orthopedics | 14 | 28 | 42 | |
| <p>*ASA=American Society of Anesthesiology **Day 8AM-5PM, Night – 5PM-8AM *** Surgery includes abdominal, thoracic, urologic, neurologic procedures.</p> | | | | | |

Table 3 Post operative complications among patients were undergoing elective and emergency surgery at University of Gondar Teaching Hospital from January to May 2013.

| | | Is SSCL attached | | Total |
|-----------------------------|---------------------------------|------------------|-----|-------|
| | | yes | No | |
| | Pneumonia | 8 | 36 | 44 |
| | Bronchitis | 4 | 4 | 8 |
| | UTI | 7 | 5 | 12 |
| Type of complication | Surgical wound infection | 12 | 55 | 67 |
| | Postoperative fever | 25 | 77 | 102 |
| | Unplanned readmission | 0 | 5 | 5 |
| Total | | 56 | 182 | 238 |

Table 4 Logistic regression model of postoperative fever

| | P.value | Odds ratio | 95% C.I | |
|--------------------------------------|---------|------------|---------|-------|
| | | | Lower | Upper |
| SSCL is attached (Yes) | 0.001 | 0.490 | 0.317 | 0.758 |
| Sex (Male) | 0.298 | 0.789 | 0.505 | 1.233 |
| Coexisting disease (Yes) | 0.522 | 1.302 | 0.581 | 2.919 |
| Urgency of surgery (Elective) | 0.242 | 0.770 | 0.497 | 1.192 |
| Prophylaxis antibiotic,(Yes) | 0.009 | 0.424 | 0.223 | 0.806 |
| Time of operation (Day) | 0.156 | 0.722 | 0.460 | 1.132 |
| Anesthesia type (General) | 0.450 | 0.828 | 0.508 | 1.351 |

Table 5 Relative incidence of bacterial species isolated from the surgical wound infection at Gondar University Hospital, from January to May 2013.

| isolated organism | Is SSCL attached? | | Total |
|---|-------------------|----|-------|
| | yes | No | |
| S. aurous | 4 | 7 | 11 |
| E.coli | 1 | 8 | 9 |
| CoNS* | 1 | 5 | 6 |
| K.pneumonia | 0 | 3 | 3 |
| P. mirabilis | 0 | 2 | 2 |
| P. volugarus | 0 | 2 | 2 |
| P.aeruginosa | 1 | 2 | 3 |
| Total | 7 | 29 | 36 |
| Remark CoNS =coagulase negative staphylococci | | | |

authors did not make direct observations during the procedure which may cause a Hawthorne effect.

Conclusion

The main postoperative complications were fever, surgical site infection, and pneumonia. The predominant bacteria causes of postoperative SSIs were *S. aureus*, *E.coli* and CoNS species. Despite checklist was not used in all operations in this cross-sectional study significant reduction in postoperative fever with a decreased number of wound complications and fewer unplanned read-missions were noticed for those who use surgical safety checklist. Further studies are required to more comprehensively assess the benefits of systematic safety checks in the hospital.

Recommendations

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. 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. Further studies will be needed to confirm our results in larger patient populations.

Authors' Statements

Competing Interests

The authors declare no conflict of interest.

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