Original Article

Role of Perioperative Surgical Safety Checklist in Reducing Morbidity and Mortality among Patients: An Observational Study

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Abstract

Background: Safe Surgery Saves Lives. Patient safety is a fundamental of good quality health care, and complications due to the health-care system are well-documented and constitute an important public health problem. Implementation of the checklist in medicine and surgery can help to decrease the risk of adverse events thus can improve patient safety. **Materials and Methods:** After the Institutional Ethical Committee clearance, a total of 500 patients were enrolled and divided into two equal groups. In Group 1 (n = 250), patients underwent surgery before regular implementation of the World Health Organization (WHO) surgical safety checklist (SSC), whereas in Group 2 (n = 250), patients underwent surgery after the WHO SSC was regularly implemented. All the patients were followed up after the surgery, and patients were looked for and compared for the postoperative complications. **Results:** We found that 27 patients (10.8%) in Group 1 and 13 patients (5.2%) in Group 2 developed major wound disruption (P < 0.05). There were 73 patients (29.2%) in Group 1 and 34 patients (13.6%) in the Group 2 who developed an infection of the surgical site (P < 0.05). There were five patients (2%) in Group 1 while none of the patients in Group 2 developed sepsis during the study (P < 0.05). **Conclusions:** We found that implementation of the WHO SSC significantly reduces surgical site infections, major disruptions of the wound, and sepsis.

Keywords: *Checklist, implementation, postoperative complications, surgical safety*

Introduction

Safety and quality is an important issue while providing health-care services.[1] As surgery plays an increasingly prominent role in health care worldwide, growing attention is being focused on the safety and quality of such care. Surgical care can prevent loss of life or limb, but it is also associated with a considerable risk of complications, including perioperative death. Patients with perioperative complications can dramatically increase the total length of hospital stay, hence costs, and even mortality rates.[2]

It is seen that nearly 10% of inpatients suffer from adverse events, almost half of which are considered to be preventable.[3] Surgical procedures present an immense risk to patients, and adverse patient outcomes are usually due to substandard nontechnical skills among the surgical staff. Thus, these skills are required to be developed and maintained constantly.

Surgery is a complex team task with a considerable number of members taking part in the patient care chain. Some of the adverse events in surgical patients can be attributed to human error and failures in communication. Some human studies conducted in the operating room have shown that the surgical outcome relies not only on the individual skills but also on the quality of teamwork.[4]

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Studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4%–0.8% and a rate of major complications of 3%–17%. These rates are likely to be much higher in developing countries.[3] Thus, surgical care and its associated complications represent a substantial burden, worthy of consideration from the public health community worldwide.

Parallels can be drawn from other high hazard enterprises, for example, avionics, where security is a need and checklists are ordinarily utilized as a strategy to minimize the individual risks. A checklist is a list of action items arranged in a systematic manner that allows the user to record the completion of the individual items.[5] It is thus possible that through the implementation of the checklist in medicine and surgery, the risk of adverse events can be diminished thus improving the patient safety.[6] In 2008, the World Health Organization (WHO) published guidelines identifying multiple recommended practices to ensure the safety of surgical patients worldwide and on the basis of guidelines, the WHO developed 19 items of surgical safety checklist (SSC) [Figure 1] to improve perioperative safety, which has been shown to reduce rates of perioperative mortality and complications in a range of health-care settings.

However, the use of SSC in developing countries is still in infancy. In resource poor settings, poor organizations can increase the burden of perioperative complications. The use of SSC can ensure the safety of surgical patients and hence can help to decrease the perioperative complications.

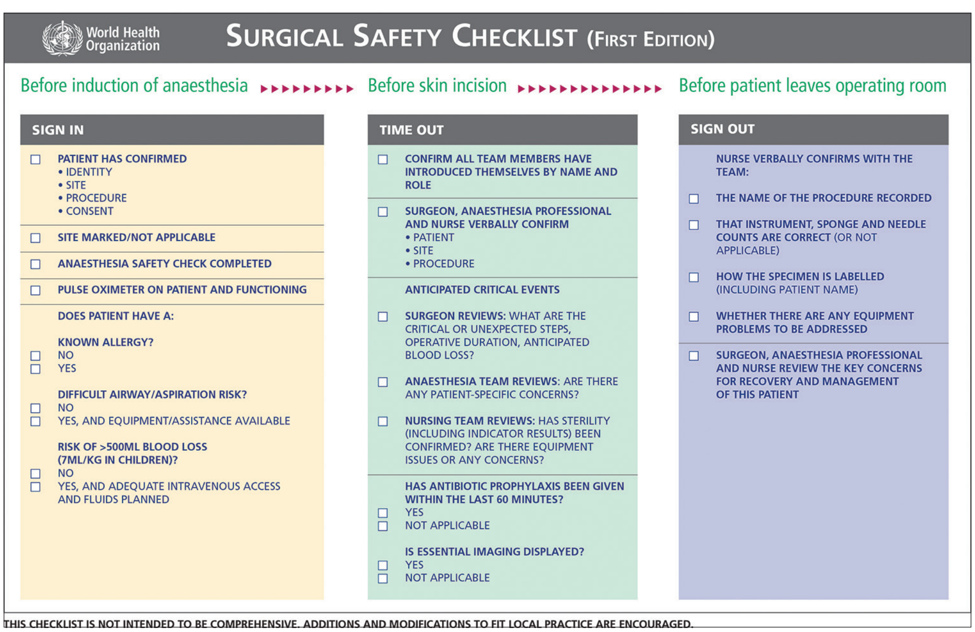
The present prospective study was planned to evaluate the effect of implementation of WHO's SSC in reducing morbidity and mortality among surgical patients being operated in the tertiary level government hospital.

Materials and Methods

After the Institutional Ethical Committee clearance, the present prospective study was conducted on the patients who visited or were referred to the Department of Surgery in the tertiary care hospital in a rural area over a period of 1 year and underwent elective surgical procedure. Written informed consent was obtained from each patient before enrolling them into the study. A total of 500 patients were enrolled and divided into two equal groups. In Group 1 ($n = 250$), patients underwent surgery before regular implementation of the WHO SSC, whereas in Group 2 ($n = 250$), patients underwent surgery after the WHO SSC was regularly implemented. Patients undergoing emergency surgeries and with duration >3 h were excluded from the study.

For implementation of the WHO SSC, boards showing the WHO SSC were installed at the nursing station/preoperative area and the surgery operation theaters (OTs). Whiteboards for counting instruments, mops, gauzes, and needles were fixed in the OTs. Around 1000 WHO SSCs were printed on A4 size and issued to resident doctors of all surgery units and OT technicians. Consultant and resident doctors of the Department of Surgery and anesthesia were sensitized about the use and importance of SSC and instruments count board.

All patients were followed up immediately after the surgery and thereafter on the 1st, 7th, 21st, and


World Health Organization
SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ PATIENT HAS CONFIRMED
• IDENTITY
• SITE
• PROCEDURE
• CONSENT

☐ SITE MARKED/NOT APPLICABLE

☐ ANAESTHESIA SAFETY CHECK COMPLETED

☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
• PATIENT
• SITE
• PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ THE NAME OF THE PROCEDURE RECORDED

☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)

☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)

☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Figure 1: Surgical safety checklist

30th postoperative days. The outcome was measured by the surgery residents those who were not involved in the study. Patients were looked for following postoperative complications:

1. Wrong site surgery
2. Difficult intubation – (if a normally trained Anesthesiologist needed >3 attempts or >10 min for successful endotracheal intubation)
3. Bleeding requiring blood transfusion of four or more units
4. Acute renal failure – diagnosed if any one of the following was present-increase in serum creatinine level by ≥0.3 mg/dL (≥26.5 μmol/l) within 48 h or increase in serum creatinine level to ≥1.5 times baseline, which had occurred within the prior 7 days or urine volume <0.5 ml/kg/h for 6 h
5. Deep vein thrombosis
6. Pulmonary embolism
7. Stroke
8. Myocardial infarction
9. Pneumonia defined as new lung infiltrates plus clinical evidence that the infiltrate is of an infectious origin, which included the new onset of fever, purulent sputum, leukocytosis, and decline in oxygenation
10. Unplanned intubation during hospital stay
11. Ventilator support for 24 h or more
12. Major wound disruption was labeled if the two sides of a surgical site would come apart with intact organ space
13. Infection of surgical site
14. Systemic inflammatory response syndrome:
    If two or more of the following variables were present
    - Fever of >38°C (100.4°F) or <36°C (96.8°F)
    - The heart rate of >90 beats/min
    - Respiratory rate of >20 breaths/min or arterial carbon dioxide tension ($PaCO_2$) of <32 mm Hg
    - Abnormal white blood cell count (>12,000/μL or <4000/μL or >10% immature [band] forms).
15. Sepsis – The presence of SIRS in addition to a documented or presumed infection
16. Unplanned return to the operating room
17. Coma of 24 h duration or more
18. Cardiac arrest requiring cardiopulmonary resuscitation (CPR).

Any mortality was considered at the end point of particular observation.

The data thus collected were systematically collected, compiled in Microsoft Excel sheets, and then analyzed using appropriate statistical methods. Statistical homogeneity was assessed by the Pearson's Chi-square tests of homogeneity. A value of $P < 0.05$ was considered to be statistically significant.

Results

A total of 500 patients with 250 patients each in two groups were enrolled in the study. In the present study, age-related and gender distribution were same in both the groups and was not statistically significant ($P > 0.05$) [Tables 1 and 2]. Both the groups were also comparable in terms of types and duration of surgery ($P > 0.05$) [Tables 3 and 4]. Complications noted on the postoperative follow-up are shown in Table 5.

Table 1: Age distribution

Age group (years)	Group 1	Group 2	*P*
Up to 10	76	57	0.05448
>10-20	24	14	0.9149
>20-30	21	26	0.44354
>30-40	24	35	0.12729
>40-50	36	41	0.53559
>50-60	35	38	0.70398
>60	34	39	0.52657
Total	250	250	

P<0.05 significant, *P*<0.001 highly significant, *P*>0.05 not significant

Table 2: Gender distribution

	Male, *n* (%)	Female, *n* (%)	*P*
Group 1 (*n*=250)	132 (52.8)	118 (47.2)	0.418
Group 2 (*n*=250)	141 (56.4)	109 (43.6)	
Total (*n*=500)	273 (54.6)	227 (45.4)	

P<0.05 significant, *P*<0.001 highly significant, *P*>0.05 not significant

Table 3: Types of surgeries

Surgery type	Group 1	Group 2	*P*
Urological surgeries	50	54	0.6594
Breast surgeries	35	34	0.89683
Gall bladder, CBD surgeries	27	25	0.76952
Hernia surgeries	25	28	0.66296
Stoma reversal	12	11	0.83095
Anorectal malformations	10	4	0.10384
Other abdominal surgeries	44	35	0.26981
Thyroid surgeries	2	2	
Others	45	57	
Total	250	250	

P<0.05 significant, *P*<0.001 highly significant, *P*>0.05 not significant. CBD: Common bile duct

Table 4: Duration of surgery

Duration	Group 1	Group 2	*P*
Up to 1 h	125	118	0.53109
>1 h up to 2 h	108	114	0.58916
>2 h up to 3 h	17	18	0.86086
Total	250	250	

P<0.05 significant, *P*<0.001 highly significant, *P*>0.05 not significant

Table 5: Overall complications

Complication	Group 1 (*n*=250)	Group 2 (*n*=250)	*P*
Wrong site surgery	0	0	
Acute renal failure	2	0	0.156
Bleeding requiring BT of 4 or more units	2	0	0.156
Difficult intubation	0	0	
CPR	5	4	0.736
Coma of 24 h duration or more	0	0	
Deep vein thrombosis	0	0	
Myocardial infarction	1	2	0.562
Unplanned intubation	6	5	0.76
Ventilator support for 24 h or more	2	2	
Pneumonia	1	0	0.316
Pulmonary embolism	0	0	
Stroke	0	0	
Major wound disruption	27	13	0.021
Infection of surgical site	73	34	0.00002
Sepsis	5	0	0.024
Systemic inflammatory response syndrome	1	0	0.316
Unplanned return to operating room	14	7	0.118
Mortality	7	5	0.558

P<0.05 significant, P<0.001 highly significant, P>0.05 not significant. BT: Blood transfusion, CPR: Cardiopulmonary resuscitation

Discussion

Complications during health-care services are well-documented and constitute an important public health problem.[7] The WHO SSC is a tool that was created over the period of 2 years with international inputs from experts in surgery, anesthesia, infectious diseases, epidemiology, nursing, biomedical engineering, and quality improvement to reduce the number of errors and complications resulting from surgery. This study attempted to provide the effect of the implementation of the WHO SSC on surgical outcomes. The WHO SSC divides the operation into three phases, each corresponding to a specific time period in the normal flow of a procedure namely the period before induction of anesthesia (Sign In), the period after induction and before surgical incision (Time Out), and the period during or immediately after wound closure but before removing the patient from the operating room (Sign Out).

Age and gender are important factors which can affect the surgical outcome. In this study, age- and gender-related distribution was comparable in both the groups (P > 0.05) [Tables 1 and 2]. Both the groups were also comparable in terms of type and duration of surgery (P > 0.05) [Tables 3 and 4].

In this study, none of the patients in any of the groups was operated on the wrong site, have difficult intubation, and have coma of 24 h duration or more, DVT, pulmonary embolism, or stroke [Table 5].

Both the groups showed statistically insignificant (P > 0.05) results in regard to postoperative acute renal failure, blood transfusion, CPR, myocardial infarction, unplanned intubation, ventilator support, pneumonia, systemic inflammatory response syndrome, unplanned return to operation table, and mortality [Table 5].

In this study, we found that there were 27 patients (10.8%) in Group 1 who developed major disruption of the wound while there were 13 patients (5.2%) in Group 2 who developed major wound disruption. The higher incidence of major wound disruption in Group 1 was statistically significant (P < 0.05) [Table 5].

Gawande *et al*. in their study found that 4% of all surgical adverse events were wound problem (noninfectious) of which 53% could be prevented.[8] de Vries *et al*. in their study found that 1.5% of patients developed wound complication in the baseline group and 0.8%in the checklist group (P = 0.008). Patients who developed dehiscence were 0.9% in the baseline group and 0.4% in the checklist group.[6]

Surgical site infection (SSI) is an important and preventable surgical complication. Various preventive measures are being adopted like timely administration of prophylactic antibiotic which can help to reduce SSI. In this study, we found that there were 73 patients (29.2%) in Group 1 who developed an infection of the surgical site while there were 34 patients (13.6%) in Group 2 who developed an infection of the surgical site. The higher incidence of infection of surgical site in Group 1 was statistically significant (P < 0.05) [Table 5].

Gawande *et al*. in their study found that 11.2% of all surgical adverse events were wound infection of which 23% are preventable.[8] Haynes *et al*. also in their study found that 6.2% of patients developed SSI which declined to 2.7% after checklist implementation.[3] Weiser *et al*. in their study found that 11.25% of patients developed SSI in the baseline group which has declined to 6.6% after checklist implementation.[9]

Thus the implementation of the checklist is associated with a significant reduction in wound complications. The reasons could be ensured sterilization and ensured antibiotic administration prophylaxis in the last 60 min in patients with mandatory use of the checklist. Dimovska-Gavrilovska *et al*. in their study found that the administration of parenteral antibiotics before surgery reduces the incidence of postoperative infections after neurosurgical procedures, especially in cases with increased risk factors for SSIs.[10]

Surgical patients are vulnerable to infectious complications due to several reasons. Sepsis is a common complication in the postoperative period, and prompt recognition combined with early interventions is an effective way of reducing mortality in this condition. The suppression of the immune system after surgery predisposes the patients to develop sepsis. The postsurgical immunosuppression may be related to the direct effects of anesthetic drugs, hormonal changes related to stress, occurrence of ischemia, and reperfusion extent of surgical trauma and effects of hemorrhage and transfusion. The underlying illness, comorbidity, and factors such as age or gender also play a pivotal role in modulating the immune system and the development of sepsis.[11]

There were five patients (2%) in Group 1 who developed sepsis following surgery, while none of the patients in Group 2 developed sepsis during the study. The higher incidence of sepsis in Group 1 was statistically significant ($P < 0.05$) [Table 5].

Bellomo *et al*. in their study found that 6.5% of all serious adverse events were sepsis.[12] Khan *et al*. in their study found that 1.3% of patients developed an infection which includes septicemia.[13] de Vries *et al*. also in their study found that 4.8% of patients developed infection in the baseline group and 3.3% in the checklist group ($P = 0.006$).[6]

The present study highlights the importance of implementation of SSC in the government setup tertiary care hospital. We found a statistically significant reduction in the incidence of SSI, major wound disruption, and sepsis after the implementation of SSC. A similar study done by Chaudhary *et al*. showed that the implementation of the modified SSC was associated with a decrease in mortality (10 vs. 5.7%; $P = 0.04$) and number of complications.[14]

Surgery is a complex team task with a considerable number of members taking part in the patient care chain. Good communication is vital for safe patient care and team functioning, not only in the operating room but also in all areas of health care. Retained sponges, wrong site operations, mismatched organ transplants, or blood transfusions can be the result of interpersonal dynamics, where communication and collaboration breakdowns occur among operating room team members. Hence, it is important that clinicians should develop and use some communication tools that allows all team members to speak up and express concerns in unsafe situations.[15] Lingard *et al*. also found that the preoperative team checklist is an efficient tool that promotes information exchange and team cohesion.[16]

Pugel *et al*. in their study found that the use of the SSC improves communication and reduces complications. However, they also insisted that it require support of all the team members to make checklists beneficial in improving the patient outcomes.[17]

Thus, checklists are easy, inexpensive, and reliable tool that can be used for decreasing medical error and improving overall standards of patient care, particularly during stressful conditions when memory, vigilance, and cognitive functions can be affected. It is especially relevant in a developing country such as India where most of the population pays out of their pocket for health expenses.

However, this study has some inherent limitations such as small sample size, nonconsideration of comorbidities, a wide range of age, and diverse surgical conditions. Moreover, due to the nature of intervention planned, both the groups were not run simultaneously. Hence, a large multicenter parallel group study focusing on particular age group and particular surgery can add on to the significance of the study.

Conclusions

We conclude that SSC is an inexpensive tool and implementation of SSC helps in statistically significant reduction in the incidence of SSI, major wound disruption, and sepsis after surgery.

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Conflicts of interest

There are no conflicts of interest.

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