



Statistical analysis on Surgical Safety Guidelines and Measures

Shalabh Gupta^{1*}, Akshay Joel Yuhanna², Manisha Gupta³, Tripta S Bhagat⁴

¹⁻⁴Santosh Medical College, Santosh Deemed to be University, Ghaziabad, Uttar Pradesh 201002

*Email: drshalabhupta1@gmail.com

ABSTRACT

The surgical center is configured as a complex sector, where machines and humans live side by side, and the latter requires the efficiency of the first. High perfection and absence of errors determine a stressful environment, given that men are not machines and, although thorough and responsible, are liable to error. It is estimated that nearly 234.2 million major surgical procedures are undertaken every year worldwide. The aim of the study was to determine the effectiveness, compliance, and critical factors for the successful initiation and implementation of World Health Organization's Safe Surgery Checklist (WHO SSC) in surgical theaters in a tertiary care teaching hospital. The present study was an observational, prospective, and cross-sectional study conducted at Santosh Medical College and Hospital, Ghaziabad (Uttar Pradesh). The study was conducted from August 2016 to December 2018. Sign in was not recorded 2% of the times, time out and sign out was not recorded 2.5% of the times among all surgical procedures conducted. The major reasons were the behavioral issues (1.5%) and inadequate staff (2.0%), followed by negligence (1.5%) in our setup. Operating rooms are a unique environment within the healthcare system; the majority of operating room errors result from a lack of communication and patient safety initiatives must focus on improving intra-operative communication.

Keywords: WHO, Surgical safety, OT cases, Safety guidelines, Safety measures

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INTRODUCTION

Existing evidence suggests that seven million patients suffered surgical complications annually, 50% of which were preventable [1]. The surgical procedure is developed by a multidisciplinary team, with different functions, but not independent, and research has shown weakness in safety [2]. The team develops different activities working in an environment dominated by pressure, stress and anxiety resulting from risk situations that may corroborate the occurrence of incidents [3]. Since the Institute of Medicine published 'To Err Is Human', a significant focus in surgery has been to identify strategies to improve patient safety and prevent postoperative complications and adverse events.

The World Health Organization (WHO) surgical safety checklist developed from the WHO Global Safety Challenge "Safe Surgery Saves Lives" campaign [4] and has decreased the mortality and complication rates in the perioperative period [5]. Humans are fallible and this Checklist enhances consistency in surgical team performance at critical times, fostering good communication, teamwork, and a culture of patient safety. The simplicity of the checklist has been cited as a benefit that allows for rapid (within 1 month) and effective implementation without significant cost [6]. The checklist has garnered significant worldwide enthusiasm, with programs implemented in 26 countries and more than 3,000 hospitals worldwide within 3 years of its introduction [7]. Although effective implementation strategies have been proposed, the high degree of variability in operational and cultural factors among hospitals, surgical services, and surgical team members requires flexibility and even modification of these strategies. Quantitative and qualitative assessment questionnaires have been used to assess surgical team members' perspectives and attitudes toward quality improvement and patient safety initiatives and to identify communication gaps between surgical team providers [8].

Further, there isn't enough evidence regarding implementation of the WHO SSC in any of the tertiary care hospitals in Northern India, which further warrants the need for implementation of this safety checklist in this region. The study aims to determine the effectiveness, compliance, and critical factors for the successful initiation and implementation of the World Health Organization's Safe Surgery Checklist (WHOSSC) in surgical theatres in a tertiary care teaching hospital. To determine the compliance with the Safe Surgery Checklist (frequency and completeness). To identify the factors influencing the compliance and effectiveness of the Safe Surgery Checklist.

MATERIAL AND METHODS

Place of study- Department of General Surgery, Santosh Medical College & Hospital, Ghaziabad.

Duration of study- August 2016 to December 2018.

Study design- The present study is an Observational, Prospective, and cross-sectional study.

Sample size- 200

Inclusion Criteria:-

Patients of all age groups.

Patients of both genders.

Patients undergoing elective operative procedures.

Patients undergoing secondary surgery.

HIV, HbsAg, HCV positive patients.

Exclusion Criteria:-

Patients are unwilling to be a part of the study.

Patients undergoing emergency procedures.

Patients undergoing minor procedures under Local Anesthesia.

Method of Data Collection:-

A total of 200 patients of any age and/or gender requiring major surgical intervention not having any pre-existing complications were included in the study, and were further evaluated using WHO Surgical Safety Checklist (2009).

Statistical Analysis:-

Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) for Windows (version 24.0). Categorical variables were described as frequency (percentage), mean \pm standard deviation was used for continuous parameters. Differences between two groups were compared by the Student T test.

For non-parametric variables, the data are presented as median (min-max). In this case, the nonparametric Mann-Whitney test was used for statistical comparisons. Categorical variables were compared between two or more groups using the Chi-square test. For all analyses, a two-tailed p-value of <0.05 was considered statistically significant.

RESULT AND DISCUSSION

The age-wise distribution among patients showed that the age of study subjects was in the range of 22-65 years (fig 1). The mean age of the study group was 44.32 ± 12.06 years. The 18-30-year age group had 11 participants, 31-the 40-year-old group had 41 participants, 41-50-year-old had 82 participants, 51-60-year-old had 54 participants and the > 60 -year-old group had only 12 participants. The gender-wise distribution in study subjects showed that the majority of them were females (77.5%) and 22.5% were males (fig 2). The type of surgical procedure was conducted among all the patients. The major proportion of patients had undergone general surgical procedures (69%), followed by orthopedic surgery (20%), ophthalmic surgery (6%), and ENT surgeries (5%) (Figure3). Among the number of not filled checklists, the major reasons were the behavioral issues (1.5%) (people not intending to fill/check the SSC compliance), inadequate staff (2.0%) (existing staff feels that they need more personnel for this task), and negligence (1.5%) (Figure4). Details of unfilled components of the WHO SSC Checklist. The sign in component was not filled 2% of the times, and the sign out and time out components was not filled nearly 2.5% of the times (Figure5). First component of the WHO SSC Checklist "Before induction of anesthesia" (Total number of patients in which checklists was NOT marked = 5 (2.5%) (fig 6). Second component of the WHO SSC Checklist "Before skin incision". (Total number of Patients in which checklists was NOT marked = 5 (2.5%)(fig 7). Third component of the WHO SSC Checklist "Before patient leaves the operating room". (Total number of Patients in which checklists was NOT marked = 5 (2.5%)(fig 8). The distribution of overall complications post-surgical intervention. Overall, a total of 6% patients suffered from post-operative complications (n=12). The distribution of post-operative complications included similar cases of infection (2.5%) and unplanned return to OR (3.5%) (Fig. 9). The details of overall errors detected post-operative causing complications. It was noticed that the errors encountered were antibiotics not given (1.5%), equipment issues (1.5%), inappropriate procedure (1.0%), radiographs not displayed (1.0%), and other issues (1.0%) (Fig.10).

The study was an observational, prospective, and cross-sectional study among patients of both genders and among all age groups undergoing major surgical procedures conducted in Department of General Surgery, Santosh Hospital & Medical College, Ghaziabad (Uttar Pradesh).

We found that all items of 'Before induction of anesthesia' component achieved over 97.5% compliance, which is similar to the study by Tan et al in China in 2021 [9]. The WHO Guidelines for Safe Surgery 2009

highly recommends that that 'before inducing anesthesia, the anesthetist should consider the possibility of large-volume blood loss' and explains that 'the expected blood loss will be reviewed again by the surgeon before skin incision' [10].

Similarly, for the second subset of SSC, the compliance was similar among all the components. It was noticed that in 99.5% of surgeries, the exact role of the team members was confirmed, antibiotic prophylaxis was provided, and critical events were mentioned. Further, in 99% of the surgeries, the name, site and procedure were confirmed to all the staff, and essential imaging was displayed in the theatre. This shows the importance of conducting the checklist, as these important items would have been forgotten if not for the checklist and that would have put the patient at risk [11].

From the available literature in the past, it is proven that compliance to the checklist is paramount in increasing the effectiveness of the checklist and in bringing a safety culture to the Operation Room [12]. The present study has provided us with an opportunity to take measures to further increase the compliance to our checklist, to encourage the interaction between the team members, and to be actively involved with greater participation and ownership of the process.

The training on checklist use must be included in a larger teamwork and communication training program. Simply providing education on the checklist alone is not enough to change the underlying safety culture of the organization [13-14]. The training should also include simulations of various difficult scenarios to allow team members to role-play. The checklist itself should be designed for usability by modifying the checklist to meet the needs of the individual organization [15].

Additionally, the checklist must be visible to all team members simultaneously in order to promote a team approach to the use of the checklist. Finally, compliance must be monitored through observation and feedback specific to the local setting on outcomes should be provided to team members. Based upon compliance reporting, a system of consequences must be in place for low compliance.

Although the sample for this study is small, the anonymous design of the survey allowed respondents to answer the questions honestly without fear of repercussions. This study is not without its limitations. The survey methodology allows for participant bias where participants may respond with answers they view as desirable by the researcher. Future research should consist of a larger scale survey to provide a more accurate picture of possible differences between the settings. The findings from this study can be used to develop safety initiatives and interventions tailored to meet the needs of the different settings.

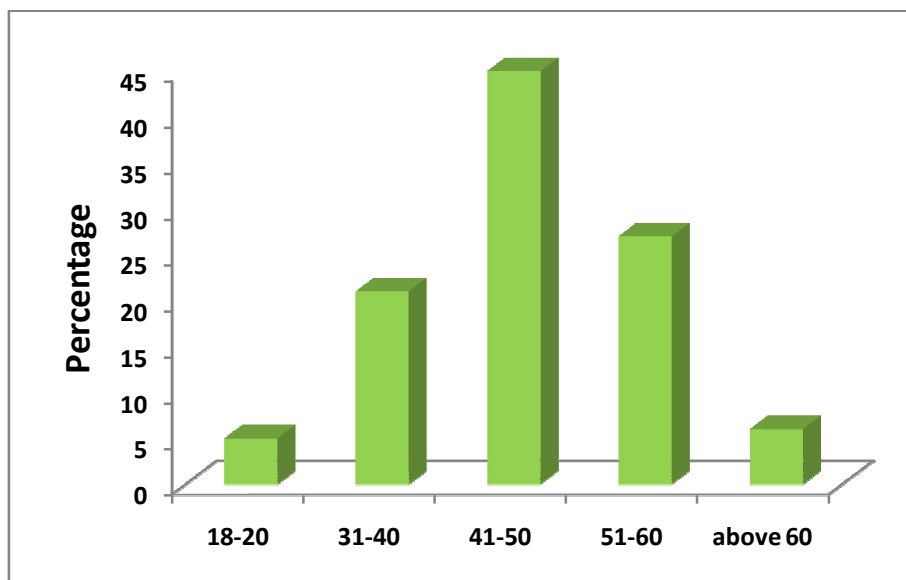


Figure 1. Frequency of Age-wise distribution

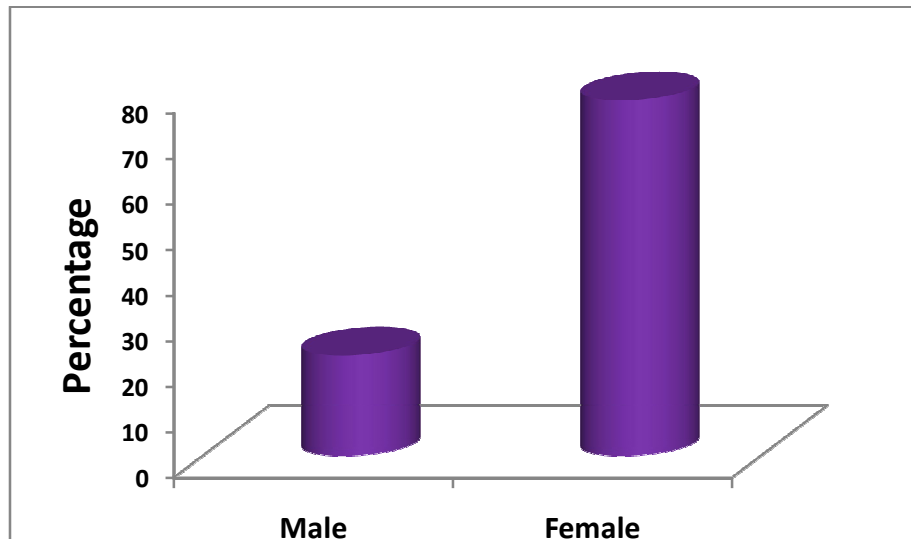


Figure 2. Frequency on Gender-wise distribution



Figure 3. Reasons excluded filling the checklist

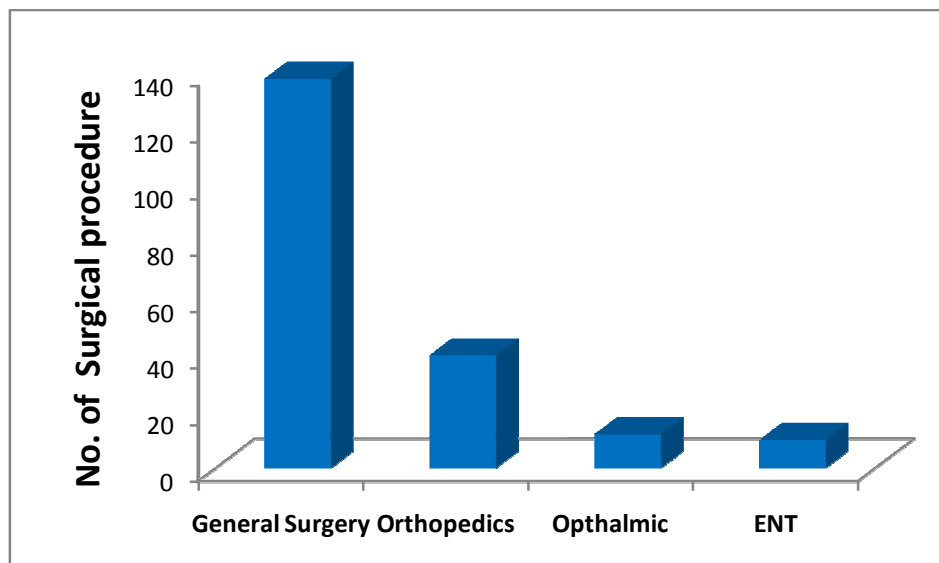


Figure 4. Number of different surgical procedure studied

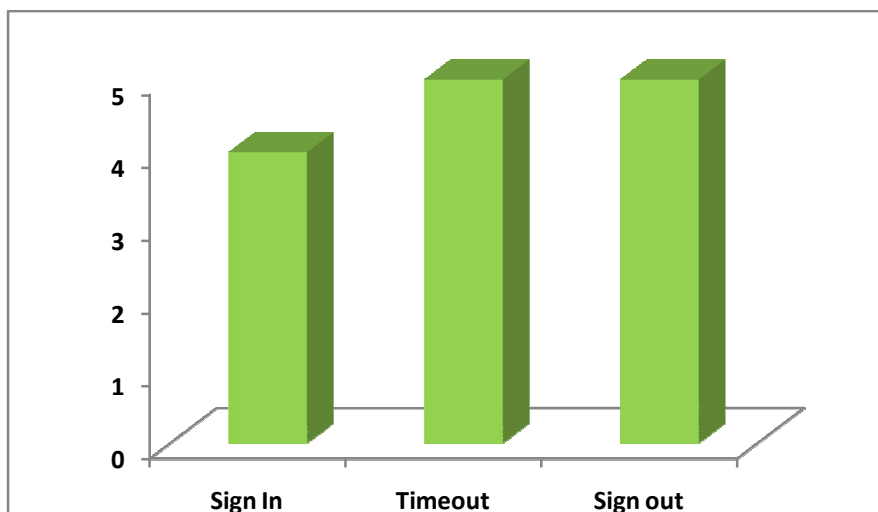


Figure 5. Unfilled components of the SSC Checklist

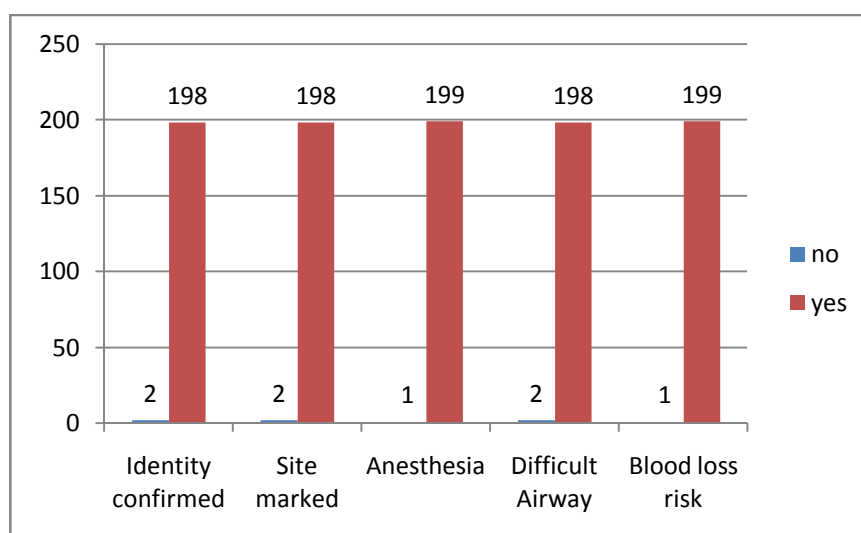


Figure 6. Before induction of Anesthesia

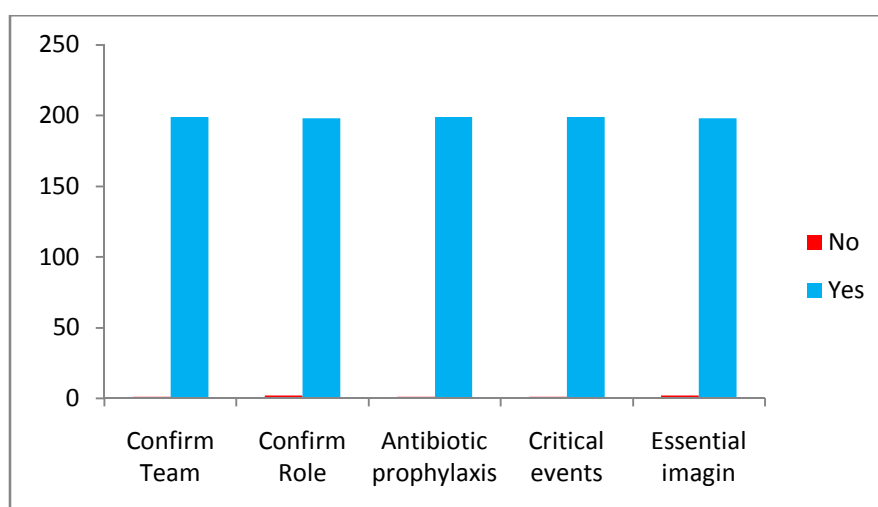


Figure 7. Before skin incision

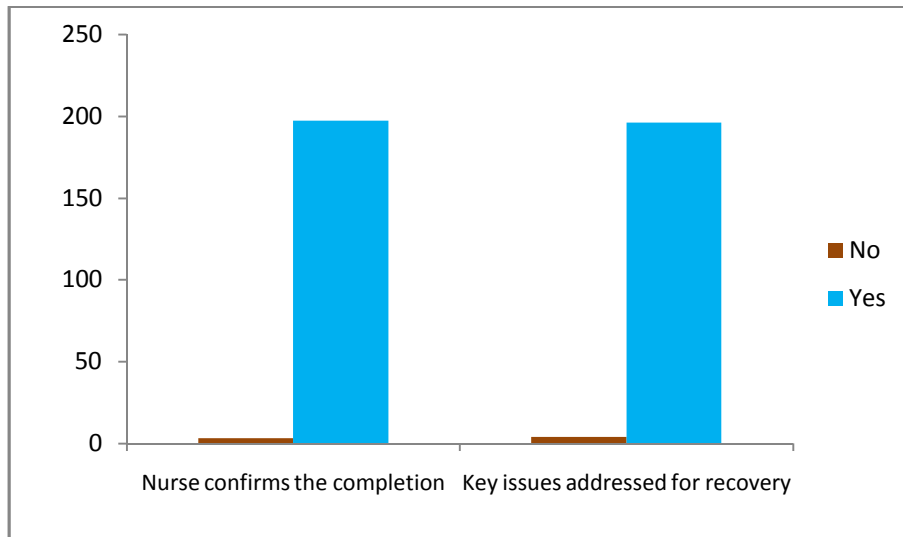


Figure 8. recovery completion and key issues

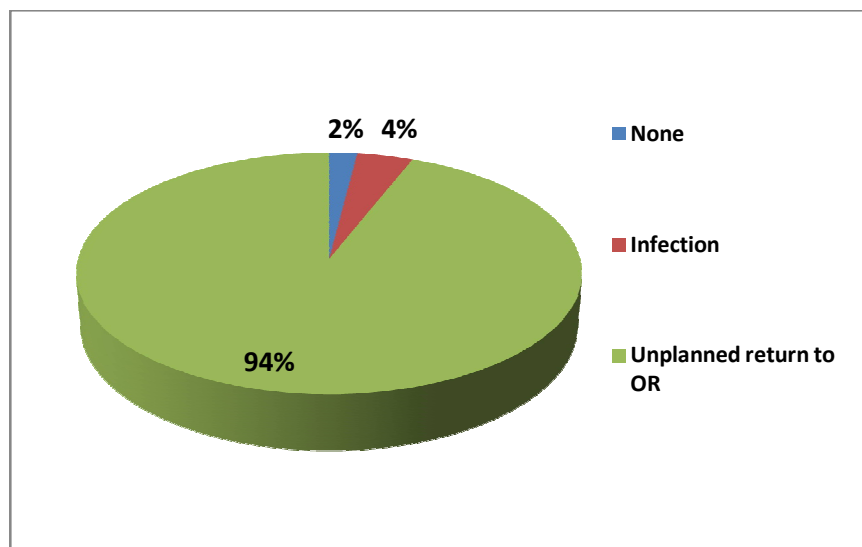


Figure 9. Percentage of Post operative complications

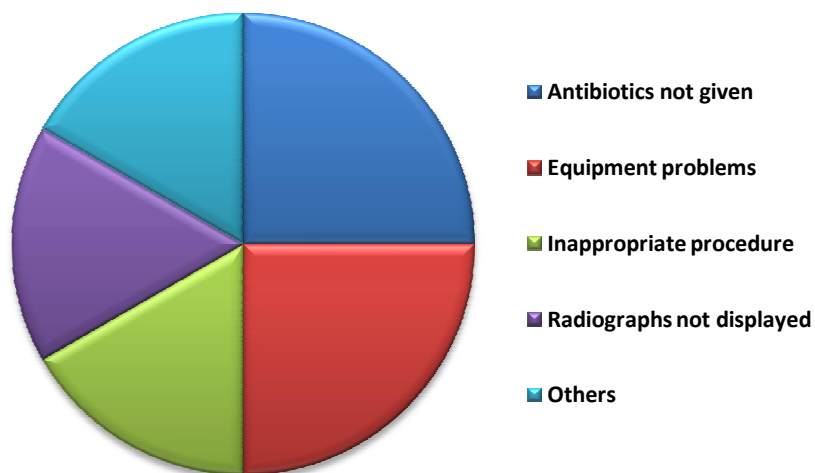


Figure 10. Errors Detected during study

CONCLUSION

Surgical safety check list is a must tool for every hospital. This helps for better communication in the operation theater. Timely execution of surgical safety check list prevents many mishaps in the hospital. But it should be administered in a perfect manner as designed to detect any miss out on preoperative assessment or to prevent any adverse outcomes.

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