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Impact of a World Health Organization (WHO) Surgical Safety Checklist Implementation During Urgent Operations on Compliance with Basic Standards of Care and Occurrence of Complications

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Abstract

Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable. Use of the WHO Surgical Safety Checklist has been shown to be associated with significant reductions in complications and deaths. A 19-item surgical safety checklist was implemented to reduce complications and deaths associated with surgery as well as increase the compliance with basic standards of care .The aim of this study is to assess the effect of implementation of a 19-item World Health Organization (WHO) Surgical Safety Checklist in urgent operations on compliance with basic standards of care as indicated by adherence to 6 selected safety measures and rates of complications at National Bank Hospital for the integrated care affiliated to the Egyptian Ministry of Health and Population. To fulfill this aim a prospective pre- and post intervention study design was used. A total of 60 adult male & female patients undergoing urgent operations are recruited to this study divided into two equal and matched groups (study& control). Three tools were utilized for data collections; 1) Socio-demographic and operative data sheet, 2) Complications monitoring sheet and 3) Performance of the 6 specified safety measures check list. The study results revealed a statistically significant differences regarding the incidence of complications among the two groups (χ^2 = 7.17, at p = 0.007). As well there were a highly statistically significant differences among the two groups (χ^2 =15.55 at p=0.000) regarding all safety measures performed. In conclusion, Surgical Safety Checklist implementation seemed to have a positive impact on the reductions in complications and death rates as well as increase the compliance with basic standards of care. Therefore, replication of this study on a larger probability sample would be of great beneficence to patients and health professionals.

Key words: Surgical Safety Checklist **&** urgent operations.

1- Introduction

Patient safety is one of the nation's most pressing health care challenges. A 1999 report by the Institute of Medicine estimates that as many as 44,000 to 98,000 people die in U.S. hospitals each year as the result of lapses in patient safety. (Agency for Healthcare Research and Quality, National Institutes of Health 2012). Patients undergoing urgent surgical intervention are at increased risk for complications and death. Even routine surgery requires the complex coordination of surgeons, anesthesia providers, nurses, and support staff to provide timely and effective care; heightened patient acuity and time pressure increase the potential for critical errors and omissions in established standards of care. (Weiser, et.al.2010).

Surgical care is an integral part of health care throughout the world, with an estimated 234 million operations performed annually. Surgery is performed in every community: wealthy and poor, rural and urban, and in all regions. The World Bank reported that in 2002, an estimated 164 million disability-adjusted life-years, representing 11% of the entire disease burden, were attributable to surgically treatable conditions. (Debas, et.al.2006). Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17%.These rates are likely to be much higher in developing countries. (Gustilo, et.al. 2009) Thus, surgical care and its attendant complications represent a substantial burden of disease worthy of attention from the public health community worldwide. (Bickler, et.al. 2009). Data suggest that at least half of all surgical complications are avoidable. A growing body of evidence also links teamwork in surgery to improved outcomes, with high-functioning teams achieving significantly reduced rates of adverse events. (Dellinger, et.al. 2005). In 2008, the World Health Organization (WHO) published guidelines identifying

multiple recommended practices to ensure the safety of surgical patients worldwide. On the basis of these guidelines, a 19-item checklist was designed intended to be globally applicable and to reduce the rate of major surgical complications. (World Health Organization, 2008).

Implementation of the World Health Organization's 19-item Surgical Safety Checklist improved the process of care and was associated with a one-third decrease in complications across all types of noncardiac adult surgery(Haynes,et.al. 2009). In situations requiring urgent intervention, however, there has been worry that use of a checklist will interrupt workflow and delay therapeutic care in ways that increase risk to patients. Delays are recognized to increase risk in the treatment of appendicitis and open fractures, for example. Nonetheless, these delays are measured in hours rather than minutes and a brief perioperative checklist may avert errors that are common in urgent surgery. (Bickell, et.al. 2010). So this study hypothesized that implementation of this checklist in urgent surgical cases would improve compliance with basic standards of care and reduce rates of death and complications following surgery in one of Egyptian Ministry of Health and Population's hospital.

Operational definition: urgent operations defined as an operation required within 24 hours of assessment to be beneficial for saving life or limb.

Aim of the Study

The aim of the study was to assess the effect of implementation of a 19-item World Health Organization (WHO) Surgical Safety Checklist in urgent operations on compliance with basic standards of car as indicated by adherence to 6 selected safety measures and rates of complications at National Bank Hospital for the integrated care affiliated to the Egyptian Ministry of Health and Population.

2- Subjects and Methods

Research Design

A prospective pre- and post intervention study design was used to accomplish aim of this study.

Sample and Setting

A total of 60 adult male & female patients undergoing urgent operations will be recruited to fulfill the aim of this study. The sample will be divided to two equal groups, study and control (30 subjects each). Those who are agreeing to join in the study will be included in the study. Matching criteria of both groups will be selected according to age, gender, procedural category, and urgency of the operation. The present study was conducted at operating rooms of the National Bank Hospital for the integrated care affiliated to the Egyptian Ministry of Health and Population.

Tools of Data collection

After reviewing related literature to fulfill the aim of the study, three different tools were designed by the research team and revised by the consultants. The study tools were constructed, tested and piloted by the investigator to examine their applicability, clarity, reliability and feasibility for data collection, then revised by a panel of medical surgical nursing and general surgery experts. Also content validity and expert's opinion were taken into consideration and the needed modifications were carried out and Face Validity of the tools was examined through a jury of three experts. These tools are: Socio-demographic and operative data sheet, Complications monitoring sheet and Performance of the 6 specified safety measures check list.

A- Socio-demographic and operative data sheet:

This tool consists of 7 items covering two main sections: the first one is related to the biographical and social data such as age and gender. The second section covers operative data such as procedural category, wound classification and urgency of the operation.

B- Complications monitoring sheet:

This sheet was designed to study the expected complications after urgent abdominal operations. It includes 19 main complications; acute renal failure, bleeding requiring 4 units of red cell transfusion within 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma for 24 hours, deep venous thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours, pneumonia, pulmonary embolism, stroke, major wound disruption, surgical site infection, sepsis, septic shock, systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, and death. The scores of this tool ranging from 0 to 19 the greater the score the greater the complications occurred.

C- Performance of the 6 specified safety measures check list

The researcher assessed completion of a subset of 6 safety measures as an indicator of process adherence. These measures were: objective evaluation and documentation of patient airway prior to anesthetic; use of pulse oximetry at the time of initiation of anesthesia; presence of at least 2 peripheral intravenous lines or a central venous catheter before incision in cases with an estimated blood loss of at least 500 mL; administration of prophylactic antibiotics within 60 minutes before incision except in cases with pre-existing infection, where no incision was made, or when operating in a contaminated field; verbal confirmation of patient identity, operative site, and procedure immediately before incision; and completion of a surgical sponge count in cases

where an incision was made. The researcher created an adherence score based on the composite of all 6 of these safety measures. The scores of this tool ranging from 0 to 6 the greater the score the greater adherence to safety measures.

Procedure

To accomplish the aim of the study three phases were utilized. Preparatory, implementation and evaluation phases.

1-Preparatory phase: This phase was concerned with assessment of patient's setting and assessment and analysis of the operating rooms staff members' perspectives in regard to the newly admitted check list in order to carry out the study in addition to construction and preparation of different data collection tools, as well as obtaining official permission from the director of the National Bank Hospital and ethical review of the study was obtained.

2-Implementation phase: once an official permission was obtained from. A total number of 60 patients who fulfilled the criteria of inclusion were recruited into the present study. For ethical consideration The researcher begin with the control group (30 patients) up to the end of their follow up period then begin with the study group (30 patients) to be in a different time. Collecting base line data before introducing the check list from 30 included patients (control group) through introducing the three study tools over a period of 4 months. Then introducing the check list to operating rooms staff members through lectures, written materials and direct monitoring from the investigator, introduction of the check list into the study rooms occurred over a period of 2 weeks, then the investigator begin to introduce the study tools for the other 30 patients (study group) over a period of 4 months. 3- Evaluation Phase: Each patient either in the study or the control group had been met several times; after admission, preoperatively, during operation, and immediate postoperatively up to 2 days after operation to enable the investigator to obtain the needed data that could confirm the patients' condition and Presence of complications. While the nurse's adherence to the 6 preset safety measures was observed during the operation with both control and study groups.

Statistical Analysis

Data analysis was performed using Statistical Package for the Social Science (SPSS version.16) was used for statistical analysis of the data, as it contains the test of significance given in standard statistical books. Statistical significance was considered at P- value< 0.05

3. Results

Findings of the current study are presented in three main sections: The first one represents Socio-demographic and operative data, the second one is concerned with incidence of Complications and the third one related to the Performance of the 6 specified safety measures.

Section I: Socio-demographic and operative data

This section represents findings related to biographical and social data such as age and gender and operative data such as procedural category, wound classification and urgency of the operation. Table (1) shows that more than half of the study group was female while more than half of the control group was female (60% & 53.3% respectively). The highest percentage of both groups age from more than 30 to 40 years old (36.7%),the same table revealed that the highest percentage of procedural category were colorectal operation followed by obstetric and abdominal GI operations (23.3% & 20 % respectively) while the lowest percentage was related to vascular and thoracic operations with the same percentage (3.3%). Regarding wound classification the same table showed that more than half of study and control groups had clean wound (53.3% & 80% respectively) with no statistical significance differences between two groups. Related to the urgency of the operation the same table denoted that the majority of both groups had immediate operation (76.7%) with no statistical significance differences between two groups.

(Table 1): Socio-demographic characteristics and operative data of both study and Control Group Subjects as regards to Gender , Age, procedural category, Wound classification and Urgency of the operation (n=60).

Variables	Study group		Control group		χ^2	P-value
	n	%	n	%		
Gender						
▪ Male	12	40	16	53.3	0.721	0.602 N.S
▪ Female	18	60	14	46.7		
Age/yrs						
▪ 19 – 30	3	10	3	10	0.00	1.00 N.S
▪ < 30 – 40	11	36.7	11	36.7		
▪ < 40 – 50	9	30	9	30		
▪ < 50 – 60	5	16.7	5	16.7		
▪ < 60 – 70	2	6.7	2	6.7		
Mean ± SD	41.63± 10.92		41.90± 10.78			
Procedural category						
▪ Trauma	4	13.3	4	13.3	0.00	1.00 N.S
▪ Obstetric	6	20	6	20		
▪ Orthopedic	3	10	3	10		
▪ Vascular	1	3.3	1	3.3		
▪ Thoracic	1	3.3	1	3.3		
▪ Abdominal GI	6	20	6	20		
▪ Colorectal	7	23.3	7	23.3		
▪ Urology/ Gynecology	2	6.7	2	6.7		
Wound classification						
▪ Class I; clean	16	53.3	24	80	5.80	0.21 N.S
▪ Class II; clean-contaminated	6	20	3	10		
▪ Class III; contaminated	3	10	2	6.7		
▪ Class IV; Dirty infected	2	6.7	0	0		
▪ Unclassified	3	10	1	3.3		
Urgency of the operation						
▪ Immediate	23	76.7	23	76.7	0.00	1.00 N.S
▪ Urgent	7	23.3	7	23.3		

Section II: incidence of complications

Regarding the incidence of complications , the current study indicated that, more than three fourth of the study group (80%) developed no complication while around half of the control group (53.3%) developed complication with a highly statistically significant differences (χ^2 = 7.17 , at p = 0.007). regarding the death rate only minority (3.3%) of the study group was died while (13.3%) of the control group were died with no statistical significance differences between two groups (χ^2 =1.96, at p = 0.16). as shown in (table 2). Regarding the total complications scores among the two studied groups (table 3) revealed that, the majority of the study and control groups developed no complications (80% & 46.7% respectively) with statistically significant differences (t= 2.33, at p = 0.023).

(Table 2):Percentage Distribution of Complications Developed among the Two Studied Groups throughout the study periods (n=60).

Variables	Study group		Control Group		χ^2	p-Value
	N	%	N	%		
Occurrence of any complication						
1.yes	6	20	16	53.3	7.17	0.007*
2.no	24	80	14	46.7		
Death						
1.yes	1	3.3	4	13.3	1.96	0.16 N.S
2.no	29	96.7	26	86.7		

* Significant at the ≤ 0.05 probability level

(Table 3):Comparison of Total Complications Scores among the Two Studied Groups throughout the study periods (n=60).

Variables	Study group		Control Group		t	p-Value
	N	%	N	%		
Total complications scores						
0	24	80	14	46.7	2.33	0.023*
1	3	10	9	30		
2	2	6.7	4	13.3		
3	1	3.3	2	6.7		
4	0	0	1	3.3		
	0.33± 0.75		0.90± 1.09			

Section III: Performance of the 6 specified safety measures.

Regarding the adherence to 6 selected safety measures performed for the two studied groups (table 4) denoted that there were statistically significant differences regarding Objective Airway Evaluation, Two IVs or Central Line Present at Incision when EBL≥500mL, Prophylactic Antibiotics Given Appropriately and Verbal Confirmation of Patient and Operative Site with (χ^2=5.93at p=0.01 , χ^2=5.71 at p=0.01 ,χ^2= 11.915 at p=0.001 and χ^2=10.80 at p=0.001 respectively) while there were no statistically significant differences regarding Pulse Oximeter Used and Sponge Count Completed (χ^2=2.30at p=0.129 and χ^2=0.88at p=0.347 respectively). As regards the all safety measures performed, the same table revealed that there were a highly statistically significant differences among the two groups (χ^2=15.55 at p=0.000). Table (5) denoted that regarding the comparison of total safety measures performed scores among the study and control groups their mean scores (5.06± SD = 1.17 and 0.90± SD = 1.09 respectively) and there were a highly statistically significant differences(t=6.227 at p= 0.000).

Table 4):Percentage Distribution of adherence to 6 selected safety measures performed for the two studied groups throughout the study periods (n=60).

Variables	Study group		Control Group		χ^2	p-Value
	N	%	N	%		
Objective Airway Evaluation					5.93	0.01*
yes	24	80	15	50		
no	6	20	15	50		
Pulse Oximeter Used					2.30	0.129 N.S.
yes	28	93.3	24	80		
no	2	6.7	6	20		
Two IVs or Central Line Present at Incision when EBL≥500mL					5.71	0.01*
yes	23	76.7	14	46.7		
no	7	23.3	16	53.3		
Prophylactic Antibiotics Given Appropriately						
yes	25	83.3	12	40	11.915	0.001*
no	5	16.7	18	60		
Verbal Confirmation of Patient and Operative Site						
yes	26	86.7	14	46.7	10.80	0.001*
no	4	13.3	16	53.3		
Sponge Count Completed						
yes	25	83.3	22	73.3	0.88	0.347 N.S.
no	5	16.7	8	26.7		
All safety measures performed						
yes	28	93.3	14	46.7	15.55	0.000**
no	2	6.7	16	53.3		

* Significant at the ≤ 0.05 probability level

(Table 5):Comparison of Total safety measures performed Scores among the Two Studied Groups throughout the study periods (n=60)

Variables	Study group		Control Group		t	p-Value
	N	%	N	%		
Total safety measures performed Scores						
2	0	0	3	10	6.227	0.000**
3	5	16.7	17	56.7		
4	4	13.3	8	26.6		
5	5	16.7	0	0		
6	16	53.3	2	6.7		
	5.06± 1.17		0.90± 1.09			

4. Discussion

Surgery has become an integral part of global health care. Surgical complications are common and often preventable. We hypothesized that a program to implement a World Health Organization (WHO) Surgical Safety Checklist during urgent operations can improve compliance with basic standards of care and reduces rates of Complications and deaths associated with urgent surgery. Regarding the incidence of complications, the current study pointed out that, more than three fourth of the study group developed no complication while around half of the control group developed complication with a highly statistically significant differences. However, the current study findings are in agreement with a study done by Haynes, et.al (2009) where highlighted that the risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a rate of major complications of 3 to 17%. These rates are likely to be much higher in developing countries. These findings are in agreement with a study conducted by Semel et.al (2011who reported that use of the World Health Organization's Surgical Safety Checklist has been associated with a significant reduction in major postoperative complications after inpatient surgery. The checklist generates cost savings once it prevents at least five major complications. Using the checklist would both save money and improve the quality of care in hospitals throughout the United States.

As regards the death rate the current study pointed out that only minority (3.3%) of the study group was died while (13.3%) of the control group were died with no statistical significance differences between two groups (χ^2 =1.96, at p = 0.16). The results were matched with Kaderli, et.al.(2010) who denoted that, the rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (P = 0.003). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist (P<0.001). Regarding the adherence to 6 selected safety measures performed for the two studied groups the study results denoted that, there were statistically significant differences regarding Objective Airway Evaluation, Two IVs or Central Line Present at Incision when EBL≥500mL, Prophylactic Antibiotics Given Appropriately and Verbal Confirmation of Patient and Operative Site while there were no statistically significant differences regarding Pulse Oximeter Used and Sponge Count. As regards the all safety measures performed, results revealed that there were a highly statistically significant differences among the two groups. regarding the comparison of total safety measures performed scores among the study and control groups their mean scores and there were a highly statistically significant differences). These findings are in agreement with a study conducted by Scott, et.al. (2013) who reported that, surgical safety checklists, have been shown to improve performance on a variety of patient safety measures. The results revealed that One item (procedure to be performed) achieved > 95% compliance. Three items (surgical site; availability of necessary blood products, implants, devices; and start of antibiotics) achieved 80%-95% compliance. Seven items achieved < 80% compliance (presence of required members of procedure team, presence of person who marked patient, patient identity, side marking, relevant images, allergies, and discussion of relevant special considerations). Compliance with the four core time-out items was 78.2%. Of the 11 items on the time-out being evaluated, there was a statistically significant difference between medical student and nursing observations for 10 items (p < .05).

Also this results supported by Fudickar,et.al. (2012) in The 20 studies that analyzed included a single prospective randomized trial concerning the effect of the WHO checklist on safety-related behavior in the operating room. The two surgical outcome studies documented a relative improvement of perioperative mortality by 47% in one study (from 56 in 3733 cases [1.5%] to 32 in 3955 cases [0.8%]) and by 62% in the other (from 31 in 842 cases [3.7%] to 13 in 908 cases [1.4%]), as well as a relative improvement of perioperative morbidity by 36% in one study (from 411 in 3733 cases [11.0%] to 288 in 3,955 cases [7.3%]) and by 37% in the other (from 151 in 842 cases [17.9%] to 102 in 908 cases [11.2%]). Improved interdisciplinary communication was also found. Factors that aided effective use of the checklist included exemplary implementation by team leaders

and structured training. In the same line Vries, et.al. (2010) revealed that in a comparison of 3760 patients observed before implementation of the checklist with 3820 patients observed after implementation, the total number of complications per 100 patients decreased from 27.3 (95% confidence interval [CI], 25.9 to 28.7) to 16.7 (95% CI, 15.6 to 17.9), for an absolute risk reduction of 10.6 (95% CI, 8.7 to 12.4). The proportion of patients with one or more complications decreased from 15.4% to 10.6% (P<0.001). In-hospital mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8% (95% CI, 0.6 to 1.1), for an absolute risk reduction of 0.7 percentage points (95% CI, 0.2 to 1.2).

5. Conclusion

Based on the findings of the study it is concluded that: Implementation of the Surgical Safety Checklist was associated with concomitant reductions in the rates of death and surgical complications among adult patients undergoing urgent noncardiac surgery as well as increase the compliance with basic standards of care.

Recommendations:

- The WHO Surgical Safety Checklist should be understood not merely as a list of items to be checked off, but as an instrument for the improvement of communication, teamwork, and safety culture in the operating room, and it should be implemented accordingly.
- Use of the WHO Surgical Safety Checklist in urgent operations is feasible and should be considered.

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