

How safe is the patient in the orthopedic OT? – An evaluation of compliance of surgical safety checklist

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Abstract

Patient safety is of paramount importance especially in the present day scenario. It has emerged as a new discipline. One of the ways of ensuring this in the operating theatre is by following a surgical safety check list, given by the WHO and adapted by institutions. We have analyzed the compliance of this in the orthopedic major operating theatre and have found that it is adhered to very strictly. This has minimized most of the errors such as side and site of surgery to zero percent. We strongly recommend the adherence to a similar surgical safety checklist in all institutions with busy operating theatres, such that many errors could be nullified and patient's safety is ensured.

Keywords: Patient safety, Orthopedic theatre, Surgical safety checklist, Compliance.

Introduction

Patient safety is a new healthcare discipline that emphasizes the reporting, analysis, and prevention of medical error that often leads to adverse healthcare events. The occurrences of such avoidable adverse events in patients were never documented until the late 90s, when suddenly many countries started reporting a significant number of patients who had suffered morbidity and mortality due to medical errors. Recognizing that healthcare errors impact about ten percent of patients worldwide, the World Health Organization calls patient safety a matter of major concern.

Patient safety has emerged as a distinct healthcare discipline supported by a scientific framework which has not fully developed. The discipline itself transcends many specialties and is borrowing and applying knowledge gained from other industry and business, adopting new and different technologies, and enhancing error reporting systems and analyzing the same, like root cause analysis of adverse events, preventing hospital acquired infections, morbidity and mortality audits and the like.

The safety of a patient is of paramount importance and the same has been the guiding light for doctors since the time of Hippocrates, who gave the statement "Primum non nocere" – first do no harm. In a hospital, the patient has the risk of being harmed at various

points and an operating room is one of them, where the most serious errors can occur.

A surgical safety checklist is intended to minimize errors in the operating room. These can be errors of side, site, identity, wrong procedure, etc. Since the introduction of this concept, errors in the operating room are minimized in most institutions worldwide. The concept is relatively new and extremely simple, but its application makes a huge difference in bringing down patient morbidity and mortality.

The compliance to the surgical safety checklist measures the process (as in an industry) of surgery, and refers to the percentage of surgeries in which the complete three-phase surgical safety checklist was performed correctly for every patient who undergoes surgery in the major operating theatre. The surgical safety checklist is considered performed when the nurse designated to perform the checklist (generally the circulating nurse) confirms that surgical team members have addressed all of the necessary tasks such as discussing blood loss, specific anesthesia risk and items in each of the three phases – 'sign in', 'time out' and 'sign out' – of the checklist, based upon the checklist adapted from the WHO guidelines at the Ramaiah Medical College Hospital.

The percent compliance is calculated as follows:

$$\frac{\text{\# of times all three phases of the surgical safety checklist was performed}}{\text{Total surgeries}} \times 100 = \% \text{ compliance}$$

In this study, we have assessed the compliance of the surgical safety checklist in the Ramaiah Medical College Hospital in the major orthopedic elective theatre.

Aim of the Study

The main aim of this study is to assess the compliance of the surgical safety checklist in the Ramaiah Medical College Hospital, and its impact on the patient safety and minimizing errors.

Objectives

This study was performed with the following objectives:

1. To highlight the issue of patient safety in the present day healthcare scenario
2. To evaluate if the surgical safety checklist is adequate to prevent errors and the impact of its introduction
3. To assess the compliance of the surgical safety checklist in our hospital

Review of Literature

A brief review of current literature regarding the subject of surgical safety checklist and its compliance in PubMed revealed more than 900 journal articles across the globe. This just emphasizes the fact that a subject that is relatively recent has gained so much attention, that it is apt to discuss it during the course of any study involving management of healthcare in a population. A few prominent articles have been highlighted in this review of literature.

Nugent E, Hseino H, Ryan K, Traynor O, Neary P, Keane FB have in their nationwide study in Ireland in 2012 have stated that adherence to a surgical safety checklist in all hospitals in Ireland has not been implemented in all hospitals in Ireland, though it has been introduced. The hospitals where it is introduced has seen a decline in mishaps and to be associated with an improvement in team communication (72 %), a positive change in team behavior (63 %), an increase in the consistency of patient care (82 %) and a positive culture of safety in theatre (81 %). They also concluded that the SSC has not been implemented throughout all operating departments in Ireland. Where it has been introduced there has been a perceived positive change in safety culture. However, overall greater education, endorsement, teamwork, and communication will be required to optimize the potential benefits associated with this safety instrument. In order to properly determine the benefit of the SSC following its implementation, a formal audit of morbidity and mortality is required.¹⁸

Borchard A, Schwappach DL, Barbir A, Bezzola P have performed a systematic review of available literature after analyzing 4997 citations and selecting 22 articles for review. They have stated that with the use of checklists, the relative risk for mortality is 0.57 [95% confidence interval (CI): 0.42-0.76] and for any complications 0.63 (95% CI: 0.58-0.67). The overall compliance rate ranged from 12% to 100% (mean: 75%) and for the time out from 70% to 100% (mean: 91%). They concluded that checklists are effective and economic tools that decrease mortality and morbidity. Compliance of surgical staff with checklists was good overall. Further research in particular relating to implementation is needed.¹⁹

Bliss LA, Ross-Richardson CB, Sanzari LJ, Shapiro DS, Lukianoff AE, Bernstein BA, Ellner SJ while

studying 30 day outcomes after using a surgical safety checklist in USA concluded that use of a comprehensive surgical safety checklist and implementation of a structured team training curriculum produced a statistically significant decrease in 30-day morbidity. Adoption of a comprehensive checklist is feasible with team training intervention and can produce measurable improvements in patient outcomes.²⁰

Walker IA, Reshamwalla S, Wilson IH while assessing the impact of surgical safety checklists stated that the concept of using a checklist in surgical and anaesthetic practice was energized by publication of the WHO surgical safety Checklist in 2008. It was believed that by routinely checking common safety issues, and by better team communication and dynamics, perioperative morbidity and mortality could be improved. The magnitude of improvement demonstrated by the WHO pilot studies was surprising. These initial results have been confirmed by further detailed work demonstrating that surgical checklists, when properly implemented, can make a substantial difference to patient safety. However, introducing surgical checklists is not as straightforward as it seems, and requires leadership, flexibility, and teamwork in a different way to that which is currently practiced. Future work should be aimed at ensuring effective implementation of the WHO surgical safety checklist, which will benefit our patients on a global scale.²⁴

Thus by reviewing literature from different sources across different surgical specialties, anesthesiologists, nursing staff, from developed countries like US and Sweden, to developing countries like Thailand, we get a brief idea as to the importance of having a surgical checklist and complying with it.

Materials and Methods

The orthopedic department of our institution has seen a steady increase in the number of surgeries over the years and the major operating theatre has witnessed 4692 orthopedic procedures since Jan 2013 to Dec 2016. To ensure proper care and also to minimize errors in the operating room, especially due to patients with similar names and also similar problems, the surgical safety checklist was introduced in April 2012. The surgical safety checklist has become like a reflex for all the healthcare staff at present.

The surgical safety checklist has been formulated specifically for the Ramaiah Medical College Hospital, and is adapted from the WHO surgical safety checklist. It has three components, one to be filled at the sign in, one during the commencement of procedure, the time out, and the third at sign out, when the patient is being shifted out of the operating room.

This study was performed after about six months down the line, to check regarding the compliance of the surgeons, anesthetists and the nursing staff to the performance of the tasks mentioned in the surgical

checklist. The surgical checklists of all the operated patients in the orthopedic major operating theatre on randomly selected six days were chosen, irrespective of the time of the surgery and were assessed for completeness of the checklist and signatures of the team involved in the surgical care of the patient. The surgical safety checklist was evaluated to see if any portion was left incomplete, or if any overwriting or corrections were made. We also entered the operating rooms to find out if the forms were being filled up as indicated or if they were being filled up only at the end or the beginning of the procedure. We found that the forms

were being filled up as per the requirement, and the compliance was 100%. All the 54 forms were filled up correctly and all were signed by the respective personnel. The only 2 spelling mistakes in the form were also corrected in 6 forms. The records were analyzed and tabulated.

Compliance was calculated based on the number of checklists which were fully completed, divided by the total number of surgeries performed, multiplied by 100 and expressed as a percentage.

$$\text{Thus } 54/54 \times 100 = 100\%$$

 RAMAIAH Medical College Hospital			SURGICAL SAFETY CHECKLIST		
Patient Name : Before induction of anaesthesia >>>		IP No. :	Treating Doctor :		
SIGN IN		Before skin incision >>>	Before Patient leaves operating room		
		TIME OUT	SIGN OUT		
<input type="checkbox"/> PATIENT HAS CONFIRMED • IDENTITY • SITE • PROCEDURE • CONSENT		<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM • PATIENT • SITE • PROCEDURE	NURSE VERBALLY CONFIRMS WITH THE TEAM :		
<input type="checkbox"/> SITE MARKED/NOT APPLICABLE		<input type="checkbox"/> ANTICIPATED CRITICAL EVENTS	<input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED		
<input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED		<input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS ?	<input type="checkbox"/> THE INSTRUMENT SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)		
<input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING		<input type="checkbox"/> ANAESTHESIA TEAM REVIEWS : ARE THERE ANY PATIENT SPECIFIC CONCERNS ?	<input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)		
DOES PATIENT HAVE A KNOWN ALLERGY ?		<input type="checkbox"/> NURSING TEAM REVIEWS : HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED ? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS ?	<input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED		
<input type="checkbox"/> NO <input type="checkbox"/> YES		HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES ?	<input type="checkbox"/> BLOOD & BLOOD PRODUCT TRANSFUSED IN CONSULTATION WITH SURGEON <input type="checkbox"/> YES <input type="checkbox"/> NO		
DIFFICULT AIRWAY/ASPIRATION RISK?		<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT		
<input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE		HAS THE CAUTERY PLATE BEEN KEPT & CONTACT CHECKED	NAME OF THE SURGEON & SIGNATURE		
RISK OF >500ML BLOOD LOSS (7ML/LK IN CHILDREN) ?		<input type="checkbox"/> YES <input type="checkbox"/> NO	NAME OF THE ANAESTHETIST & SIGNATURE		
<input type="checkbox"/> NO <input type="checkbox"/> YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED		IS ESSENTIAL IMAGING DISPLAYED ?	NAME OF THE NURSE & SIGNATURE		
		<input type="checkbox"/> YES <input type="checkbox"/> NO			
		FOLEY'S CATHETER IN PLACE			
		<input type="checkbox"/> YES <input type="checkbox"/> NO			
		RYLE'S TUBE INTRODUCED			
		<input type="checkbox"/> YES <input type="checkbox"/> NO			

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Fig. 1:



Fig. 2:

Discussion

Patient safety is a relatively new concept in the management of patients and in the healthcare industry. More attention is being paid to minimize errors in treatment, which as per rough estimates were close to 10% at the turn of the century.

Many centuries ago, Hippocrates had recognized the potential for injuries that arise from the well intentioned actions of healers. The Hippocratic Oath was formulated in the 4th century BC and pledged to "prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone." Since then, the directive *primum non nocere* ("first do no harm") has become the backbone for contemporary medicine. However, despite an increasing emphasis on the scientific and evidence based medical practice in Europe and the United States more recently, data on adverse outcomes were not well documented and the various studies commissioned collected mostly anecdotal events.

The WHO recognizing the importance of preventing surgical errors, which are thrice more likely to harm a patient than other errors, formulated a surgical safety checklist, and also gave a manual on the implementation of the same, the link mentioned in the bibliography, for further reference.

Many developed countries and few developing countries were quick to bring these into practice, especially those which also thrived on health tourism, and indices such as compliance of the surgical safety were required to reassure patients regarding the level of healthcare and safety of the prospective patient.

In India too, accreditation agencies such as the NABH are including these and other aspects as criteria for accrediting hospitals and thus a minimum level of safety to the patient is assured.

Most countries and hospitals have adapted the WHO surgical safety checklist and modified it to their specific needs. At the Ramaiah Medical College hospital too, the checklist is made to include three aspects of sign in, time out and sign out. A copy of the same has been included.

The Sign in phase is before the commencement of anesthesia and includes confirmation of the patient's identity, site, procedure and consent. In orthopedics, the side and the site are marked out too, and the same are confirmed. Confirmation of a pre anesthesia safety check is also made. Equipment being used to monitor the patient such as pulse oximeter is checked. Any drug allergies are noted and risk of difficult airway and blood loss are ascertained. All these are verbally verified and called out loudly in the OT by the nurse in charge. She then goes on to check the same on the list.

At time out, before the skin incision, the surgeon, anesthetist and nurse orally confirm the patient (by looking at his band), site, side, procedure and any critical steps or possible adverse events. The positions of the patient, difficulties anticipated and possible time

of the procedure are also discussed. The nursing team reviews the sterilization of equipment, and mentions if any concerns are noted. Antibiotic prophylaxis given at the time of induction in our hospital is reconfirmed and also the presence of a tourniquet, cautery plate and its contact with the patient are checked. Introduction of Ryle's tube and bladder catheterization are also confirmed.

At sign out, after the completion of the procedure, the nurse verbally confirms the procedure performed, the code for the same is written in the records and any consumables and implants used are cross checked. Sponge and needle counts are cross checked, a picture of the way sponges are laid out has been included, for reference. If any specimen is collected, it is labeled correctly and the method of sending to the laboratory is crosschecked. Any blood or blood products transfused per operatively are verified and mentioned and any post-operative instructions, example maintain limb in abduction, antibiotics for 3 doses only, or epidural analgesia required or DVT prophylaxis, etc. are given. The Surgeon, anesthetist and the nurse in charge then sign the checklist.

Though all the above procedures are routinely performed in any operating room, they are sometimes overlooked since they are mundane and routine. This may sometimes be a cause for error, example there are two patients in the preoperative room, with similar names, but are undergoing different procedures, sometimes totally different surgery under a different department, and one would be taken in for the other, or in instances of bilateral pathology, example Avascular necrosis of femoral head, with only one side being symptomatic and planned for a total hip replacement, while the other is not. All of these errors would be prevented by adhering to the checklist. It adds up not more than a few minutes to the time taken, but, adds years to a patient's life.

The compliance to this checklist is assessed by noting the number of orthopedic surgical procedures where it has been completed, divided by the number of orthopedic surgical procedures performed, multiplied by 100.

In our study, the compliance was 100%. This is comparable to some other studies too, where in the compliance was found to be 100%. In most of the studies quoted in the review of literature, it has been found that adherence to this checklist has minimized errors to a large extent, but compliance itself has varied in different studies. They have also suggested that a one hour educative session has increased the compliance to a large extent.

In our hospital, the compliance is 100 %, since the nurses have been adequately trained in the same, and it takes but a few minutes to complete. It is a pleasure to watch the nurse in charge in our operating room completing the checklist with a flourish, and holding our hand and thrusting a pen in case some surgeon says

that he is not carrying one, and ensuring that the checklist is complete by the end of the procedure. Discussion with the nursing staff in the recovery room also revealed another fact- that a patient is not accepted in the recovery room until his surgical safety checklist is complete and is accompanying the patient, and no nurse would ever want to recover a patient in the corridor.

The drawbacks in this study are that the checks were performed on random occasions and it is not an ongoing study. There may have been instances in an emergency when a patient has been taken up for surgery without the completion of the sign in, though the same may have been completed later on before the patient was shifted out of the operating room.

It would undoubtedly be beneficial to any hospital to implement this simple surgical safety checklist, such that surgical errors are minimized or better still nullified.

Conclusions

From the discussion above, it would be safe to conclude that:

1. Patient safety is of paramount importance in any hospital
2. Surgical safety is one of the most important aspects
3. Surgical safety checklist is a simple and effective measure of minimizing surgical errors
4. Compliance to a surgical checklist can very easily be motivated
5. A continuous audit of the surgical checklist compliance can identify areas of weakness and lead to introduction of newer measures and remedial actions.

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