

Research Article

To study the existing system of surgical safety for cataract surgery at tertiary care ophthalmic centre to implement WHO surgical safety checklist

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ABSTRACT

Background: Dr. Rajendra Prasad Centre for Ophthalmic Sciences, named after the first President of India, was established on the 10th of March, 1967 as a National centre for ophthalmic science, to provide state of the art patient care, expand human resources for medical education and undertake research to find solutions to eye health problems of national importance. Average numbers of cataract surgeries performed per month are 700 to 1000.

Methods: Anticipating implementation in 50% cases hundred cases of cataract surgery were observed to study the existing system of surgical safety followed at Dr. R.P. Center and gap analysis done, against the WHO surgical safety checklist for cataract surgery. Modified WHO surgical safety checklist for cataract surgery was developed and implemented in the centre. Barriers in implementation of surgical safety checklist were also identified, and remedial measures suggested.

Results: Significant improvement was noticed in all the parameters after introduction of modified checklist. The additional points which were added in modified surgical safety checklist were implemented in almost all the cases by the nursing staff. Overall mean compliance percentage before implementation of modified surgical safety check list at Dr. R.P.C was $37\% \pm 10.1$ ($P=0.001$). While after introduction of modified surgical safety check list the mean compliance has improved to $62.7\% \pm 10.3$, Wilcoxon rank sum test/Independent test is applied for each domain.

Conclusions: Cataract procedure is the most common surgical procedure performed in the population in India. High volume and high turnover increase the potential for errors. Compliance to surgical safety check list before intervention was 32%. After intervention in form of a focus group discussion and introduction of modified surgical safety check list has resulted in increase in the compliance rate to 67%. This study revealed that changes or additional work is not happily accepted by the staff. After six months of intervention of modified surgical safety checklist compliance rate was still high, this suggests that constant supervision and monitoring by senior staff can sustain the compliance rate.

Keywords: Cataract, WHO surgical safety checklist, Patient safety

INTRODUCTION

The World Health Organization's Patient Safety Programme created an initiative to improve the safety of surgery around the world. In order to accomplish this

goal the programme team developed a checklist with items that could and, if at all possible, should be practised in all settings where surgery takes place.^{1,2} In recent years there have been significant initiatives to improve patient safety in surgical care and specifically in cataract surgery.

In 2008, the World Health Organisation (WHO) launched the 'Safe Surgery Saves Lives' initiative to improve surgical practice globally.³

The aim of study was to study the existing system of surgical safety for cataract surgery and to do gap analysis for implementation of checklist.

METHODS

Study was cross sectional and prospective, anticipating implementation in 50% cases confidence level as 95% and precision as 10% (Absolute) minimum of 100 cases were observed. Hundred cases of cataract surgery were observed over a period of two months to study the existing system of surgical safety followed at Centre and un structure interview with key stakeholders were conducted to assess the level of awareness among Doctors and Nurses about the WHO surgical safety checklist for cataract surgery.

Gap analysis between the existing systems of surgical safety at Centre against the WHO surgical safety checklist is done by direct observation. A focus group discussion with the faculty of Dr. R.P. Center was conducted and the modified WHO surgical safety

checklist was developed for Dr. R.P. Center, based on the inputs received from the faculty members, according to cultural and institute requirements.

The modified checklist for surgical safety of cataract surgery is implemented at Dr. R.P. Center. Total 100 cases of cataract surgery were again observed over a period of two months after six months of implementation of modified WHO surgical checklist. Percentage compliance for the Modified WHO surgical safety checklist was measured. Barriers in implementation of modified WHO surgical safety checklist were identified through unstructured interview from each unit for the low compliance of implementation.

RESULTS

Data was collected in two stages i.e. before and after the implementation of modified WHO surgical safety checklist for cataract surgery (Table 1 and 2). Implementation of checklist was measured in terms of implementation of each step in the checklist. The number of surgeries where certain steps were not implemented was also recorded. The data was tabulated and was analysed by Strata 11.1 and presented in frequency, (percentage).

Table 1: Gap analysis against the WHO surgical safety checklist for cataract surgery.

Sign in (before giving anaesthesia)		
Steps as per WHO surgical safety checklist	System of surgical safety at Dr. R.P. C (N=100)	Gap analysis
Has the patient confirmed his/her		
• Identity	30%	70%
• Site	50%	50%
• Procedure	100%	0
• Consent	50%	50%
Is the surgical site marked	0%	100%
Is the anaesthesia machine and medication check complete	NA	NA
Does the patient have any known allergy	0%	100%
Difficult airway/aspiration risk(General Anaesthesia)	NA	NA
Any special requirements for positioning or draping	0%	100%
Is the patient taking warfarin or any other medication	0%	100%
Is the patient taking tamsulosin or other alpha blocker	0%	100%
Has pre-operative VTE risk assessment been undertaken	0%	100%
Time out (before start of cataract surgery)		
Parameter as per surgical safety checklist	System of surgical safety at Dr. R.P.C	Gap analysis
Have all team members introduced themselves by name and role	0%	100%
Surgeon, Scrub Nurse and Registered Practitioner verbally confirm:	20%	80%
• What is the patient's name?		
• What procedure and which eye?	100%	0%
• What refractive outcome is planned?	100%	0%
• What lens model and power is to be used?	100%	0%
• Is the correct lens implant present?	100%	0%

Anticipated variations and critical events	10%	90%
Surgeon:		
• Are there any special equipment requirements or special investigations?		
• Are any variations to the standard procedure planned or likely?	10%	90%
• Is an alternative lens implant available, if needed?	100%	0%
Anaesthetist (GA or sedation)	NA	NA
• Are there any patient-specific concerns what the patient's ASA grade is?		
• Any special monitoring requirements?	10%	90%
Scrub Nurse	20%	80%
• Has the sterility of the instrumentation been confirmed (including indicator results)?		
• Are there are equipment issues or concerns?	30%	70%
<i>Sign out (Before any member of the team leave)</i>		
Parameter as per Surgical safety checklist	System of surgical safety at Dr. R.P.C	Gap analysis
Registered Practitioner verbally confirms with the team has the name and side of the procedure been recorded	10%	90%
Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)	NA	NA
Have any equipment problems been identified that need to be addressed	30%	70%
Are any variations to standard recovery and discharge protocol planned for this patient	70%	30%

It was observed that maximum steps are not being followed by the surgical team against the WHO surgical safety checklist

Table 2: Modified surgical safety check list.

<i>Sign in (before giving anaesthesia)</i>			
Parameter as per modified WHO Surgical safety checklist for cataract	Step implemented before intervention of checklist	Step implemented after intervention of checklist	P value
Has the patient confirmed his/her Identity	30%	70%	0.002
Site	50%	80%	0.001
procedure	100%	100%	–
Consent	50%	70%	0.004
Is the surgical site marked	0%	20%	0.001
Is the anaesthesia machine and medication check complete	NA	NA	–
Does the patient have a: Known allergy	0	100%	<0.001
Difficult airway/aspiration risk (General anaesthesia)	NA	NA	–
Any special requirements for positioning or draping (for indoor patient)	0%	0%	–
History of any systemic disease like diabetes or hypertension, asthma, seizures etc)	0%	100%	<0.001
Is the patient taking warfarin /blood thinners	0%	0%	
any other medicine if yes, mention	0%	10%	0.002
Is the patient taking tamsulosin or other alpha blocker	0%	0%	–
Has pre-operative VTE risk assessment been undertaken	0%	0%	–

<i>Time out (before giving incision)</i>			
Parameter as per modified WHO Surgical safety checklist for cataract	Step implemented before intervention of checklist	Step implemented after intervention of checklist	P value
Have all team members introduced themselves by name and role	0%	10%	0.002
Surgeon, Scrub Nurse and Registered Practitioner verbally confirm: What is the patient's name?	20%	40%	0.002
What procedure and which eye?	100%	100%	<0.001
What refractive outcome is planned?	100%	100%	<0.001
What lens model and power is to be used?	100%	100%	<0.001
Is the correct lens implant present?	100%	100%	<0.001
Date of expiry checked?	100%	100%	<0.001
Anticipated variations and critical events if yes then mention Surgeon:			
Are there any special equipment requirements or special investigations?	10%	20%	0.048
Are any variations to the standard procedure planned or likely?	10%	20%	0.048
Is an alternative lens implant available, if needed?	100%	100%	0.000
Anaesthetist (GA or sedation) are there any patient-specific concerns What the patient's ASA grade is? Any special monitoring requirements? Are there any equipment issues concern?	NA	NA	
Scrub Nurse/ODP: Has the sterility of the instrumentation been confirmed (including indicator results)?	20%	80%	0.001
<i>Sign –out</i>			
Parameter as per modified WHO Surgical safety checklist for cataract	Step implemented before intervention of checklist	Step implemented after intervention of checklist	P value
Registered Practitioner verbally confirms with the team has the name and side of the procedure been recorded	10%	90%	≤.001
Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)	NA	NA	-
Have any equipment problems been identified that need to be addressed	30%	90%	<.0001
Are any variations to standard recovery and discharge protocol planned for this patient	70%	100%	<.0001
Has discharge summary is complete and is signed by resident doctor?	NA	100%	-
Is sticker of IOL pasted on it and postoperative instructions followed?	NA	100%	-
Follow up date & time mentioned?	NA	100%	-
<i>Sign in (before giving anaesthesia), Time out (before giving incision)</i>			
Parameter as per modified WHO Surgical safety checklist for cataract	Step implemented before intervention of checklist	Step implemented after intervention of checklist	P value
Have all team members introduced themselves by name and role	0%	10%	0.002

Surgeon, Scrub Nurse and Registered Practitioner verbally confirm:	20%	40%	0.002
What is the patient's name?	100%	100%	<0.001
What procedure and which eye?	100%	100%	<0.001
What refractive outcome is planned?	100%	100%	<0.001
What lens model and power is to be used?	100%	100%	<0.001
Is the correct lens implant present?	100%	100%	<0.001
Date of expiry checked?	100%	100%	<0.001
Anticipated variations and critical events if yes then mention Surgeon:	10%	20%	0.048
Are there any special equipment requirements or special investigations?			
Are any variations to the standard procedure planned or likely?	10%	20%	0.048
Is an alternative lens implant available, if needed?	100%	100%	0.000
Anaesthetist (GA or sedation) are there any patient-specific concerns			
What the patient's ASA grade is?	NA	NA	
Any special monitoring requirements?			
Are there any equipment issues concern?			
Scrub Nurse/ODP:			
Has the sterility of the instrumentation been confirmed (including indicator results)?	20%	80%	0.001
<i>Sign –out</i>			
Parameter as per modified WHO Surgical safety checklist for cataract	Step implemented before intervention of checklist	Step implemented after intervention of checklist	P value
Registered Practitioner verbally confirms with the team has the name and side of the procedure been recorded	10%	90%	≤.001
Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)	NA	NA	-
Have any equipment problems been identified that need to be addressed	30%	90%	<.0001
Are any variations to standard recovery and discharge protocol planned for this patient	70%	100%	<.0001
Has discharge summary is complete & is signed by resident doctor?	NA	100%	-
Is sticker of IOL pasted on it & postoperative instructions followed?	NA	100%	-
Follow up date & time mentioned?	NA	100%	-

Two group proportional test was applied.

Mean (S.D)/Median (Min-Max) as appropriate. Categorical variable of percentage compliance were compared after the implementation of surgical safety check list by proportion test and over all percentage compliance score was compared by independent T test/Wilcoxon rank sum test. P-value less than 0.05 were considered as statistically significant (Figure 1).

Significant improvement was noticed in all the parameters. The additional points which were added in modified surgical safety checklist were implemented in almost all the cases by the nursing staff (Table 3) Overall mean compliance percentage before implementation of surgical safety check list at Dr. R.P.C was 37%±10.1 (P=0.001).

While after intervention of modified surgical safety check list the mean compliance has improved to 62.7%±10.3,

Wilcoxon rank sum test/Independent test is applied for each Domain.

Table 3: Total average compliance rate was compared by independent T test.

Domain	Before intervention median (Min-Max)	After intervention median (Min-Max)	P-value
Sign in	41.6 (41.6-83.3)	45 (20-60)	≤0.001
Time out	41.6 (41.6-83.3)	75 (50-91.6)	≤0.001
Sign out	33.3 (0-100)	100 (33.3-100)	≤0.001

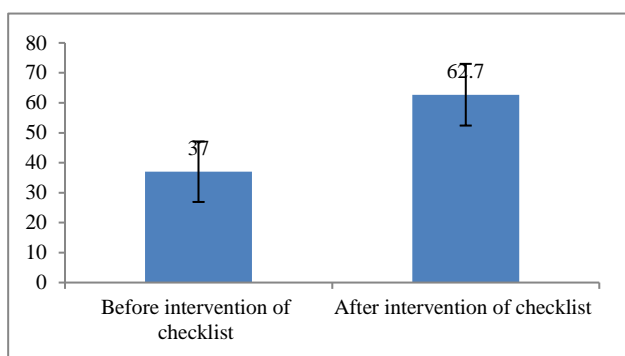


Figure 1: Compliance rate before and after intervention of modified check list.

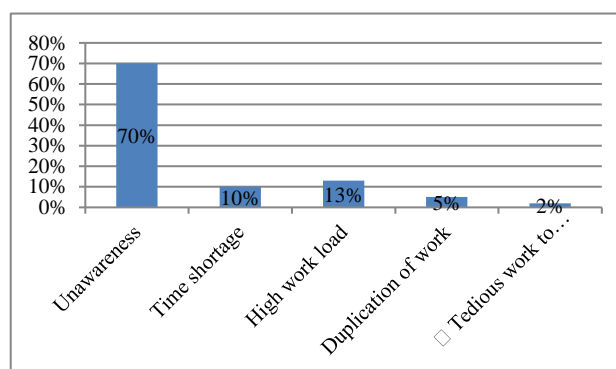


Figure 2: Barriers for implementations.

Table 4: Compliance rate before and after intervention of modified check list.

	Before intervention Mean ±SD N=100	After intervention Mean±SD N=100	Absolute improvement (95 C.I.)	P- value
% compliance	37±10.1	62.7±10.3	25.6 (22.7, 28.4)	<0.001

Total average compliance rate was compared by Independent T test (Table 3). Through unstructured interview it was found that there are certain challenges faced in implementation of modified WHO surgical safety checklist for cataract surgery (Figure 2).

DISCUSSION

It has been noticed that percentage compliance rate of implementation of parameter like history of intake of warferin, tamsulosin, VTE prophylaxis are almost nil. Medical and paramedical staff believes that these parameters are not relevant for cataract surgery.

It is also supported by implementation guide for surgical safety checklist that VTE prophylaxis are not relevant for cataract surgery but the findings of the study done by Bell C et al are contradictory to this statement which says that exposure to tamsulosin within 14 days of cataract surgery was significantly associated with serious

postoperative ophthalmic adverse events other study also revealed that most patients are elderly with concomitant medical conditions and thus vulnerable to dangers of surgery.^{22,23} For example, patients on alpha-blockers and on warfarin may increase the surgical risk.¹²

After six months of intervention of modified surgical safety checklist compliance rate was still high, this suggests that constant supervision and monitoring by senior staff can sustain the compliance rate. Some doctors think that checklist for cataract surgery is not required or filling it is time consuming while study done by Cavallini et al revealed that a high level of adherence to the surgical safety checklist could improve the management of an eye surgery operating room.¹¹ Evidence suggests that visual outcome is frequently sub-optimal in many low-income settings. Improving visual outcome is complicated and requires a holistic approach to patient care involving a focus on clinical effectiveness, patient safety and patient experience.⁷

The peer experts were also of the opinion that the documentation in the medical record should have been more consistent and detailed (e.g. relevant findings at follow-up visits).²² The policy should include the requirement to document the communication.¹⁴ As from this study barriers identified are lack of knowledge or unawareness, heavy workload, time shortage while reasons identified in other study for non-implementation are non-availability of checklists 7 (13.7%), lack of formal training 23 (45.1%), time constraint 10 (19.6%), uncooperative surgical teams 11 (21.6%).¹⁸ Hence regular training by awareness creation should be in place especially for new nursing/aesthetic staffs because of high turnover.¹⁸ The active participation of administration and nursing staff can help, the same has also been supported by the study that administrators should be encouraged to meet with staff, listen to problems, and work with them to overcome barriers.^{21,22,24}

From the result of this study it is confirmed that further detailed work on demonstrating and educating the staff about surgical checklists is required. When properly implemented, it can make a substantial difference to patient safety which was also concluded from the study.²⁵

CONCLUSION

Cataract procedure is the most common surgical procedure performed in the population in India. High volume and high turnover increase the potential for errors. Compliance to surgical safety check list before intervention was 32%. After intervention in form of a focus group discussion and introduction of modified surgical safety check list has resulted in increase in the compliance rate to 67%.

This study revealed that changes or additional work is not happily accepted by the staff. After six months of intervention of modified surgical safety checklist compliance rate was still high, this suggests that constant supervision and monitoring by senior staff can sustain the compliance rate.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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