

Near Misses" Regarding Cataract Operation In Small Incision Cataract Surgery: How Do We Rectify Understanding And Documentation?

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Abstract

Background: Aim: Near misses are widely reported to the precursors of adverse events that highlight vulnerabilities and potentially unsafe areas of practice. The aim of this study was to see if a descriptive method of recording near misses was an appropriate method for use in an ophthalmic operating theatre and to quantify how many untoward events were recorded using this system related to the cataract surgery. **Subjects and Methods:** The study was wholly conducted in a operation theatre in the HIMS, Varanasi. The operation theatre staff assigned to the patient in their journey through the operating theatre was asked to note any untoward events. As, at present, there is no consensus definition of near misses in ophthalmology the staff recorded, in free text, any events that they considered to be a deviation from the normal routine in that theatre. **Results:** 250 cataract cases were randomly enrolled, 48 "deviations from normal routine" were described in 46 patients - that is, 19% of cases. All forms distributed to the staff were returned (100% response rate). The commonest abnormal events were intraoperative (35), with a lesser number being recorded preoperatively (13). When these events were further classified, it was thought that 13 could be classified as near misses. Once true adverse event was recorded during the study. **Conclusion:** The result suggest that experienced staff in an ophthalmic theatre are a reliable source for collecting data regarding near misses. A consensus is now required to define near misses in ophthalmology and to devise a user friendly input system that can use these definitions to consistently record these potentially vital events.

Keywords: Cataract, Small incision cataract surgery.

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Introduction

Now days , Health care organizations to use near misses as sources of learning that highlight system vulnerabilities and point to opportunities for quality improvement in health care,^[1] because it is frequently found that within health systems patients can sometimes come to harm.^[2] The prevalence of iatrogenic harm has been shown to be much higher than previously thought.^[3,4] This has led, in recent years, to an increased interest in the study of patient safety within healthcare system. According "Accreditation Canada Reference Guide line" Near Misses is an event or circumstance which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage but did not actualize due to chance, corrective action, and/or timely intervention,^[1] but in a healthcare "near miss" is a situation in which an event or omission, or a sequence of errors or omissions, arising during clinical care fails to develop further (as a result of compensating action), thus preventing injury to a patient.^[2] In most hospitals, adverse incidents are reported using a central adverse incident reporting system. Few system however encompass near misses. Near misses occur more frequently than actual adverse incidents and they provide a

valuable opportunity for learning by quantitative analysis about the nature, frequency, and types of safety issues.^[3] The importance of near misses is that they can indicate where flaws in system lie. The weakness of them is that the lesson they can offer are ignored because the patient has not come to harm.

In most hospitals, adverse events are reported through an established incident reporting system tailored to individual hospitals. However, near misses are not usually systematically recorded, unlike in industry Y.^[5-8] Near misses outnumber adverse events in a relationship that was quantified over 60 years ago by Heinrich, who estimated that for every 300 near misses there would be 29 minor injuries and one major injury.+[2]

If we are to utilise lessons from near misses, we need to know how often they occur and in what circumstances. Before this can be done near miss events need to be defined on the basis of their likelihood and consequences. In ophthalmology there is, as yet, no clear definition of near misses. It is therefore difficult to subject them to quantitative methods of analysis. Other specialties have indicated that the operating theatre is one of the commonest sites of errors and near misses- and the area with the greatest potential for serious harm from these⁸. We thought

that cataract surgery represented a good model for analysing operating theatre errors- it is a common operation, complications can be sight threatening, and it has the highest indemnity claims in ophthalmology.^[10-12]

The purpose of this study was thus to devise an acceptable method of recording near misses in a operation theatre where cataract surgery performed. Since near misses in ophthalmology have not been fully defined, we decided to use a descriptive method to record experienced theatre staff perception of what they considered to be "deviation from the routine"

Subjects and Methods

The study was conducted in operation theatre of Heritage institute of medical sciences, Bhadwar, Varanasi, Uttar Pradesh. The operation theatre has an annual turnover of around 250 cataract surgery.

The system employed in this theatre is that on the day of the operation the patient is assigned a named staff called the "primary staff". The duties of the primary staff are to accompany the patient throughout their time in theatre- they are also responsible for filling in the operative notes. Because they observed the patient throughout their visit to the operation theatre but are not involved in the mechanics of the surgery, we thought them to be in the best position to record the events surrounding the operation. We thus asked the primary staff to report any event during their patient's visit to the theatre that they considered to be a "deviation from routine".

All the staff who participated in the study were trained ophthalmic staff experienced in cataract surgery. They were not asked to categorise their comments into near misses or adverse events but simply to describe events that related them as "deviations from routine" during surgery. The method of reporting was anonymous in that the staff did not need to identify themselves or any other member of the team.

A total of 250 cases in the year 2017-18 were randomly chosen. The selected patients' name, hospital identification numbers, and dates of operation were printed and distributed to the primary staff at the start of every list.

Results

All 250 distributed sheets were returned (response rate 100%). Most response sheets had "uncomplicated," "nothing to report," or "nothing untoward" written on them. Forty eight sheets had response that the staff thought describe deviations from the routine. Two patients had more than one deviation during their operation. No patients had more than two recorded. Therefore, in this study 46 (19%) patients had, what the primary staff considered to be, a deviation from the normal routine during their visit.

Although these deviations were reported by the primary staff in a descriptive manner, for ease of presentation and analysis we have categorised their response into preoperative, intraoperative, and postoperative events.

These are summarised below:

1. Preoperative "deviations from routine"

- Delay in starting operation, 6(2.5%) cases [Table 1]
- Anaesthetic problem, 2 (1%) cases [Table 2]
- Miscellaneous, 5 (2%) [Table 3]

2. Intraoperative "departures from routine"

- Extended surgery, 2 (1%) cases (more than 20 minute)
- Defective instruments, 10 (4%) cases [Table 4]
- Difficult operation, 7 (3%) cases (Appendix [Table S1])
- Complications, 13 (5%) (Appendix [Table S2])
- Miscellaneous, 3 (1%)

3. Postoperative (from completion of surgery to discharge) "departures from routine."

- No incident was documented in this study.

Table 1: Reasons for delay starting the operation

Delay due to	Number
Late Surgeon Arrival	01
Complicated procedure in previous patient	02
Delay in acquiring in patient notes	01 (NM)
No cases stated	01

Table 2: Anesthetic Problem noted

Anesthetic Problem noted	Number
Peribublar injection painful	01
Chemosis occurred	01

Table 3: Other preoperative deviations recorded

Other preoperative deviation recorded	Number
Biometry error	02 (NM)
Incorrect patient note	01 (NM)
Consent not signed by patient	02

Table 4: Defective instrument events recorded

Defective instrument events recorded	Number
Irrigation aspiration cannula blocked	04 (NM)
Defective forceps	02 (NM)
Problem with microscope setting	03
Incorrect intraocular lens no.	01 (NM)

Table 5: Recorded deviations from routine, assessment of number of near misses within this and number of adverse events

Recorded deviation from routine, assessment & no. of near misses with in the and no. o adverse events	Recorded deviation from routine	no. of near misses	no. o adverse events
Preoperative			
Delay in starting operation	06	01	00
Anesthetic problem	02	00	00
Miscellaneous	05	03	00
Intraoperative			
Extended Surgery	02	00	00
Defective instrument	10	07	00
Difficult operation	07	00	00
Complication	13	00	00
Miscellaneous	03	02	01
Postoperative	00	00	00
Total	48	13	01

After categorising these deviation, we assessed which deviation we thought could be classified as near misses and which as true adverse events. This was inevitably a subjective interpretation. Although we have given standard definitions in our introduction there remains considerable debate surrounding these definitions. The result of our deliberations are documented. Near misses (which we defined as having the potential to cause harm if correcting action was not taken) are denoted by "NM". As far as true adverse events (that is, where the patient did come to temporary or permanent harm) are concerned, we thought there was only one of these- the patient who was known to have a cefuroxime allergy and was given the drug. The patient developed some itchiness and was observed until this abated- resulting in some delay to the patients discharge. This adverse event was reported via the standard hospital system.

Appendix

Table S1: Reasons for difficult surgery

Difficulty Recorded	Number
Chemosis	01
Small pupil	03
Iris prolapse	01
Hyphaema	01
Premature entry	01

Table S2: Complication noted during surgery

Complications	Number
Posterior capsule rupture	06
Iridodialysis	01
Descemet,s detachment	01
Vitreous loss	03
Eccentric capsulorhexis	01
Excessive bleeding	01

Discussion

This descriptive study found 48 occurrences in 46 patients (out of a total of 250), which the primary staff thought deviated enough from the normal routine to record.

Although it was one of the commonest recorded events, "complications" or "difficult surgery" has been excluded from this analysis as we thought that these represented well recognised and unavoidable variations in surgical difficulty. Excluding the above, the commonest deviation was defective instrument-described in 10 cases. The most common problem was blocking of the phaco tip, followed by defective forceps and then failure of the phaco machine itself. The majority of deviations in this category we thought could be categorised as potential near misses.

A number of preoperative events could also be classified as near misses. These included biometry errors, incorrect patient notes (corrected before commencement), and (providine) iodine not available. "Delay in starting operation" cannot be called a near miss in itself but could contribute to creating an environment in which near misses/adverse events are more likely to occur.

No postoperative complications were described in this

study-this is the time the primary staff helps the patient leave the theatre before preparing them for discharge and it is likely that they had too limited a time to record any untoward events. In our study this was therefore not a useful method of recording deviation.

Overall, we assessed that 13 the "deviation" could be classified as near misses. Thus, 5% (13/250) of cases had a near miss. With one case classified as a true adverse event, we have calculated the Heinrich ratio from this study as 13:1

Usefulness of study method

Interestingly, the detection of near misses as a key step to recovering from initial failures, yet no work has explained how individuals detect initial failures and determine whether they are near misses or not. Further exploration to unravel the processes associated with detecting and differentiating near misses is required in order to inform future practice and policy strategies aimed at enhancing safety and performance in organizations. While safety science suggests that near misses are sources of learning to guide improvement efforts, the study identified how ophthalmologist cognitively downgrade and accept near misses as a routine part of daily practice. Such downgrading reduces the visibility of near misses that lead to decrease complication related to cataract surgery.^[1]

The aim of this study was to test if a simple, open ended method of recording untoward events in operation theatre would be feasible. Our response rate (100%) suggests that the method itself was efficient and that the personnel chosen (the primary staff) was best place to record these events.

The staff thought that in 19% of operations, there were deviation from the routine that were reporting. These positive response are interesting in that they provide us with information which probably would not have been documented elsewhere but could have a significant impact on the outcome of cases any operating list. The figure does need to be treated with some caution as we did not assess any deviation that the nurses either missed or did not record. Indeed, it may be speculated that they are likely to under-record these events in the "heat of the moment."

As described previously, there are, at present, no universally agreed definition of near misses in ophthalmology. This study suggests that our method may be a useful first step in creating these definition.

Few difficulty recorded such as bulging eye due to chemosis, small pupil, premature entry, Hyphaema that may lead to complications during small incision cataract surgery. Its preventable when we carefully do surgery.

The descriptive method is only really useful though as a starting point as it produces a large amount of data, not all of which may be relevant (for example, variations in surgical difficulty). For a near miss reporting system to be generalisable there needs to be a consensus from ophthalmologists, theatre staff, and other operation theatre personnel. Our definitions of near misses in this study were subjective and future work needs to use this consensus as a basis for devising a practical near miss recording system.

Conclusion

The aim of the medical profession is to provide safe, human and up to date care individualised to every patient. In order to provide our patients with a safer healthcare system, errors need to be documented, types of errors and trends and factors contributing to errors need to be identified. Near misses often appear insignificant but when analysed systematically can provide valuable information about "weak links" in a system. Our study suggests that experienced staff in an ophthalmic theatre appear to be a reliable observers and the descriptive method they used appeared acceptable.

The result of the study now need to be refined to produce a definition of important near misses related to cataract in operation theatre. Once these definition and guidelines have been devised a user friendly but flexible input system needs to be developed. This will then allow us to analyse the frequency and patterns of near misses and in the long term increase patient safety in this commonest of operations.

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