

ORIGINAL RESEARCH

Effects of poor-quality surgical instruments on patient safety and surgeon's mental health

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Received: 02 April, 2023

Accepted: 04 May, 2023

ABSTRACT

Background: Surgical decisions, particularly those involving patient health, have been re-examined in light of the recent rise in malpractice lawsuits in India and elsewhere. The first step in figuring out the frequency and pattern of these issues is to collect data on commonly occurring incidences of instrument breakdown or malfunction during operations, as these occurrences are commonly under-reported and unappreciated concerns. So, this present study was conducted with an aim to assess the effects of poor-quality surgical instruments on patient safety and surgeon's mental health. **Methods:** The present study was web-based cross-sectional study conducted in the Department of General Surgery at a Tertiary care hospital of North Maharashtra, over a period of 1 month. A pre-tested questionnaire was used with both open and close ended questions to capture the surgeon's responses. The surgeons were approached and recruited through social networking websites (Facebook, Twitter and Whatsapp). The participants were given a week's time to voluntarily complete the questionnaire and those who do not respond back to the questionnaire within defined time and reminders were declared as drop outs and were not included in the data analysis. **Results:** In our study, a total of 476 completely filled responses was received. Most of the surgeons in our study were General surgeons (38.4%), Orthopaedic surgeons (14.2%) and Superspecialists (26.1%). The working experience among 42.7% of surgeons was <5 years and 23.1% surgeons were having work experience between 5-10 years. The surgeons were also asked about the issues they face due to dysfunctional surgical instruments. It was observed that fatigue (Mental and physical) was reported by 71.2% of surgeons, Irritation and loss of concentration was seen in 92.0% and 56.1% of surgeons respectively. To improve the quality of surgical instruments the surgeons suggested use of personal set of instruments (38.2%), Preventive maintenance audits (64.3%), Gentle and careful handling (58.0%), Feedback to manufacturers and dealers (42.5%), and increasing the supply of instruments (50.5%). **Conclusion:** Poor surgical instruments quality control results in the use of subpar instruments that malfunction and break. Although using such tools was associated with a low frequency of severe damage, the results can be disastrous.

Keywords: Instruments, Break, Fragmentation, Surgery, Operative

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INTRODUCTION

The foundation of medicine is the unspoken trust that exists between doctors and patients. Physicians and Surgeons are required to follow the *primum non nocere* principle and to take the patient's best interests into account as much as possible when performing any procedure. This should serve as a guideline, especially in decisions involving unexpected complications that may arise during surgeries.[1]

As aids in surgical procedures, many instruments are used during fracture fixation surgeries. While some of these instruments are non-metallic or a combination of both, most of them are metallic. The mechanical benefit and simplicity of operation they provide are crucial for quick and uneventful surgery. Although they are more durable, made primarily of metal, and make fracture procedures simpler, surgical equipments can still fail.[2]

In the post-operative or follow-up period, there have been a number of reported issues with implants, including their breakage. It is thought that reports of instrument breakage are less frequent than the occurrences themselves. One recent multi-centric study of more than eleven thousand procedures found a reported incident rate of 0.35 percent. Most of the fractured fragments were still present and didn't produce any clinical issues. It is suggested that an organisation be created to report and handle cases similar to these because many of these incidents are brought on by subpar instruments and pose a risk to the public's safety.[3,4,5]

Surgery decisions, particularly those involving patient health, have been re-examined in light of the recent rise in malpractice lawsuits in India and elsewhere. The first step in figuring out the frequency and pattern of these issues is to collect data on common instrument breakdown during operations, as these occurrences are still mostly under-reported and unappreciated concerns.[6] So, present study was conducted with an aim to assess the effects of poor-quality surgical instruments on patient safety and surgeon's mental health.

MATERIALS AND METHODS

The present study was web-based cross-sectional study conducted in the Department of General Surgery at a tertiary care hospital of North Maharashtra. The study was conducted over the period of 1 month (January to February 2023). The study included surgeons (General surgeons, Orthopaedic surgeons, Superspecialists, Gynaecologists, ENT surgeons, Ophthalmologists and Others) with having access to the internet as study subjects.

A pre-tested questionnaire was used with both open and close ended questions to capture the surgeon's responses. The questionnaire included details such as working experience, place of work and profession. Characteristics of the Surgical instruments at workplace was also captured such as Preferred

instruments, Dysfunctional class of surgical instruments, Features for dysfunctional instruments, Intraoperative problems due to dysfunctional instruments, Reason for instrument being dysfunctional and Overall quality of surgical instruments at workplace. The outcome such as problems faced by surgeon and patients due to dysfunctional instruments, and Frequency and reasons of using poor quality instruments by surgeons was also captured. The suggestions by surgeons were also captured.

The surgeons were approached through and recruited through social networking websites (Facebook, Twitter and Whatsapp) and the password-protected survey links were posted on the same. An introductory paragraph outlining the aims and objectives of the study as well as instructions to complete the questionnaire was explained in the questionnaire. Participation in this survey was voluntary and was not compensated. Informed consent was obtained from each participant prior to participation. Sufficient time was given to participants to read, comprehend, and answer all the questions and the participants could not change the answers after submission of questionnaire. The participants were given a week's time to voluntarily complete the questionnaire and those who do not respond back to the questionnaire within defined time and reminders were declared as drop outs and were not included in the data analysis.

RESULTS

In our study, a total of 476 completely filled responses was received. The most of surgeons in our study were General surgeons (38.4%), Orthopaedic surgeons (14.2%) and Superspecialists (26.1%). The working experience among 42.7% of surgeons was <5 years and 23.1% surgeons were having work experience between 5-10 years. Most of surgeons included in the study were working in a Medical College (39.6%) followed by Tertiary care hospital or above (32.1%) (Table 1).

Table 1: Basic profile of the surgeons.

Variables	Number	%
Profession		
General surgeon	170	38.4
Orthopaedic surgeon	66	14.2
Superspecialists	111	26.1
Gynaecologist	33	7.2
ENT surgeon	30	6.6
Ophthalmologist	24	5.4
Others	42	9.3
Working experience		
<5 years	203	42.7
5-10 years	110	23.1
11-15 years	56	11.8
>15 years	107	22.4
Work place		
Private hospital	135	28.3

Medical College	188	39.6
Tertiary care hospital or above	153	32.1

In our study, we asked for the preference for the surgical instruments, 45.4% of surgeons preferred the use of Personal surgical instruments, whereas 79.2% preferred use of Hospital surgical instruments. When asked specifically about the class of surgical instruments being dysfunctional, it was observed that 46.7% reported dysfunctional Cutting surgical instruments (Blade, scalpel, scissors, bone cutter, bone nibbler, gigging saw, amputation knife), 51.9% reported dysfunctional Clamping instruments (Artery forceps, mixer, Kocher's, bowel clamps), 47.6% reported dysfunctional Electro surgical units (cautery, unipolar, bipolar, Harmonic, vessel sealer), 8.0% reported dysfunctional Accessories and implants (needles, trocars, drains and tubes) and 36.3% reported dysfunctional Laparoscopic/Orthoscopic/Endoscopic

instruments. The surgical instruments were dysfunctional due to poor hinges (56.1%) and due to old manufacturing (51.5%). Fragmentation (4.6%) and Breakage (20.4%) were reported as Intraoperative problems due to dysfunctional instruments. The surgeons were asked about Overall quality of surgical instruments at workplace. Only 7.5% of surgeons reported as Very good quality (completely trouble free). Overall quality of surgical instruments at workplace were Good (Few instruments have minor trouble), Average (few instruments have frequent troubles), Bad (many instruments with minor troubles), and Very bad (many instruments have frequent troubles and poor functioning) were reported by 36.3%, 40.6%, 10.7%, and 4.8% of surgeons respectively (Table 2).

Table 2: Characteristics of the Surgical instruments at workplace.

Variables	Number	%
Preferred instruments*		
Personal	216	45.4
Hospital	377	79.2
Rented	11	2.3
Dysfunctional class of surgical instruments*		
Cutting	222	46.6
Grasping forceps	195	41.0
Clamping instruments	247	51.9
Suturing (needle holder)	218	45.8
Electro surgical units	227	47.7
Accessories and implants	38	8.0
Laparoscopic	173	36.3
Retractors	20	4.2
Others	12	2.5
Features for dysfunctional instruments*		
Metal quality	119	25.0
Hinges	267	56.1
Finishing	99	20.8
Sterilization	150	31.5
Sharpness	40	8.4
Old	245	51.5
Intraoperative problems due to dysfunctional instruments*		
Fragmentation	22	4.6
Breakage	97	20.4
Quality	198	41.6
Effortful handling	301	63.2
Non-functional	207	43.5
Reason for instrument being dysfunctional*		
Manufacturing defects	135	28.4
Designing	101	21.2
Maintenance	412	86.6
Human error	139	29.2
Overall quality of surgical instruments at workplace		
Very good	36	7.6
Good	173	36.3
Average	193	40.6

Bad	51	10.7
Very bad	23	4.8

*Multiple responses

The surgeons were also asked about the issues they face due to dysfunctional surgical instruments, it was observed that Fatigue (Mental and physical) was reported by 71.2% of surgeons, Irritation and loss of concentration was seen in 92.0% and 56.1% of surgeons respectively. When asked about the problems faced by patients due to dysfunctional surgical instruments, 33.0% of surgeons reported No harm, while Low harm (minor surgical site infections, minor bleeding causing no major morbidity), Moderate harm (haemorrhage, major infections, injuries to adjacent structures re-exploration), and Severe harm (life threatening events due to retained products/blood

loss/sepsis) were reported by 60.8%, 22.7% and 3.8% of surgeons respectively. In our study, 8.4% of surgeons reported that they used dysfunctional surgical instruments Very frequently, whereas 20.8% of surgeons reported that they Never used dysfunctional surgical instruments. Among surgeons who were using the dysfunctional surgical instruments, the reason cited was Financial problems (9.0%), No other choice available (31.6%), Deliberately assigned poor quality instruments to junior doctors to keep good set available for seniors (9.9%), and No supervision on quality checks and cleaning process (50.3%) (Table 3).

Table 3: Outcome of using dysfunctional instruments among surgeons and patients.

Variables	Number	%
Surgeons*		
Fatigue (Mental and physical)	339	71.2
Irritation	438	92.0
Concentration loss	267	56.1
Stress due to retained products	128	26.9
Medico-legal cases	60	12.6
Confidence loss	117	24.6
Patients*		
No harm	157	33.0
Low harm	289	60.7
Moderate harm	108	22.7
Severe harm	18	3.8
Frequency of using poor quality instruments		
Very frequently	40	8.4
Frequently	79	16.6
Sometimes	110	23.1
Occasionally	148	31.1
Never	99	20.8

To improve the quality of surgical instruments the surgeons suggested Use of personal set of instruments (38.2%), Preventive maintenance audits (64.3%), Gentle and careful handling (58.0%), Feedback to manufacturers and dealers (42.5%), and Increasing the supply of instruments (50.5%).

DISCUSSION

In our study, study subjects reported incidence of surgical instruments fragmentation (4.6%) and Breakage (20.4%) as Intraoperative problems due to dysfunctional instruments. If this issue is ignored, broken surgical instruments constitute a major concern. If the findings of the aforementioned investigation are applied generally, a large number of defective instrument-related patient safety incidents will be recorded every year. Despite the absence of apparent fatalities in this sample, substantial injury was caused, necessitating several surgeries to remove the foreign object. Such reoperations come with additional risks and expenses for emergency procedures that could be very harmful. These are undoubtedly undesirable results that may be completely avoided.

In their investigation, Price et al., reported a 0.18% rate of instrument breakage. In elective instances, the rate was 0.03%, but in trauma patients, it was 0.79%. Eight of the surgical cases were carried out by residents, and 11 of the 14 broken devices were drill bits. Although the fragment was removed during surgery in 7 cases, most patients were not made aware of the circumstance.[1]

The rate of implant breakage in a multicenter trial by Pichler et al., was 0.35%. In 5 cases, the fragment was removed, and in 7, it was left in place. In the cases without removal, there were no difficulties. Only 3 of the 7 instances, however, involved the circumstance being noted in the operation note. The study's authors emphasised the need of recording implant breakages.[3]

Ward patients and the frequency of reporting patient safety issues were the subjects of a study by Sari et al.

Only 17% of occurrences were properly reported, according to their findings. It is possible to speculate that many instrument breakages occur every year, the most majority of which are not recorded, if this is extrapolated to the current condition.[7]

It should be noted, though, that incidents in operating rooms typically involve senior staff who are following strict protocols; deviation from these protocols may be more likely to prompt an incident report; as a result, it is likely that the actual number of unreported patient safety incidents is much lower. However, the ambiguity around the disparity between the number of occurrences that are reported and the actual number of incidents highlights the need for better reporting guidelines.[8,9,10]

Perhaps the lack of clarity in the reports is what is most concerning. Broken surgical instruments can be a serious issue with negative effects. In several instances, it is not specified whether X-ray imaging was utilised to determine whether surgical instruments were intact or broken and whether they were, or whether the fragments had been removed. In addition, it has been stated in a number of accounts that the treating surgeon did not think an X-ray was required. In the case of a suspected Broken surgical instrument, it would make sense to do a radiological investigation to pinpoint the issue and provide a prognosis. This not only reveals a flaw in the reporting system, which does not call for such information on the proforma, but also the requirement for instructions in the event of a suspected Broken surgical instrument, in order to record this issue and provide prognosis.[11,12,13]

The frequency of patient damage could be greatly decreased through quality assurance procedures of surgical instruments prior to their application if we agree that very few people misuse surgical instruments to the point where they surpass their design limits. In doing so, instrument breakages would be decreased.[6,14]

The necessity of enhancing production quality to stop the circulation of low-quality instruments could also be highlighted by alerting regulatory agencies and the producers themselves about substandard instruments.[15,16]

CONCLUSION

Poor surgical instruments quality control results in the use of subpar instruments that malfunction and break. Even while using such tools was associated with a low frequency of severe damage, the results can be disastrous. The dangerously high number of patient safety events involving broken surgical tools that are annually reported to regulatory agencies, along with inadequate management reporting, support the necessity for preventative and backup plans in the event of a surgical instrument breakage. To solve the

issue, it should be thought about creating a quality control system for surgical instruments and putting policies in place when there is a possible breakage.

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