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SURGERY IN LOW AND MIDDLE INCOME COUNTRIES

Analysis of Surgical Adverse Events at a Major University Hospital in South Africa

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Abstract

Background Surgical 'never events' have serious adverse outcomes for patients. A never event can be defined as a serious, avoidable patient safety incident that would not occur if necessary preventative measures are implemented. The literature from South Africa on this topic is limited. This study aims to understand these never events in our setting and to develop a taxonomy to classify these events which facilitates the development of strategies to prevent and reduce the incidence and impact of surgical never events.

Materials and methods A retrospective review was undertaken over a 5-year period (December 2012–December 2017) at the Pietermaritzburg Metropolitan Surgical Service, South Africa. All morbidities and surgical never events recorded on the Hybrid Electronic Medical Registry (HEMR) were retrieved and analyzed.

Results A total of 20,432 patient admissions were captured on HEMR, and total of 7187 morbidities were recorded. Of these morbidities, 61.6% were in males and 38.3% in females. Patients admitted to general surgery accounted for 62.7% of the total, and trauma surgery and pediatric surgery accounted for 33.6% and 3.8%, respectively, of the total number of morbidities. Of these 7187 morbidities, a total of 79 never events were identified: 53 (67.1%) in males and 26 (32.9%) in females. Of all morbidities reported, 1.1% (79/7187) constituted a never event. The rate of never events for all admissions was (79 never events/20,432 admissions) or 0.39%. Among the 79 never events, general surgery patients experienced 47 (59.5%), trauma surgery 25 (31.6%), and pediatric surgery 7 (8.9%). In addition to these 79 never events, a total of 126 near misses were identified, of which 80 (63.5%) occurred in males.

Conclusion Surgical morbidity is common and has a substantial impact of both the individual patient and society as a whole. Robust reporting mechanisms are needed to capture data, and these data must feed into evidence-based strategies to reduce the incidence and impact of this morbidity. Our systems ensure that our incidence of surgical never events is relatively low, but ongoing efforts must be made to ensure that we drive this level down even further.

Introduction

All surgical interventions are associated with morbidity, and this surgical morbidity can in many ways be regarded as a 'disease' in its own right. Surgical morbidity has a demographic profile and inflicts a significant human and financial burden on individual patients and society as a whole. Since the publication of the monograph *'To err is Human'* at the turn of the last millennium [1], there has been increased interest in studying the patterns of surgical

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morbidity and developing strategies to reduce the incidence and impact of surgical morbidity. The realization that human error contributes significantly to surgical morbidity has prompted an interest in understanding human error and how it impacts on surgical care. A never event can be defined as a serious, avoidable patient safety incident that would not occur if necessary preventative measures are implemented [2]. All never events are, by definition, entirely preventable, and as such, there is not acceptable threshold for their occurrence [2]; these errors are so egregious that they should never happen. The UK National Health Service (NHS) has an official list of never events that are defined by the National Patient Safety Agency (NPSA). These include (but are not limited to) operating on the wrong body part or wrong patient, performing the wrong procedure, leaving instruments or swabs inside a body cavity, or having the wrong prosthesis implanted [3]. Although they are referred to as never events, it is apparent that they actually do occur. An individual human is inevitably at the frontline of a patient interaction that results in a never event; however, health systems contain inherent weaknesses and are impacted negatively by external forces, which in some instances create a perfect environment for error to occur [4]. A never event must therefore be seen as a systems failure, and the root cause of such a catastrophic event includes process failures, such as a lack of communication or poor teamwork. Never events occur in well-resourced and stable healthcare systems in the developed world, but there have been very little data on never events in the developing world. This study aims to review the surgical never events at a major University Hospital in South Africa. It aims to classify and understand these never events and to use this information to develop evidence-based strategies to prevent and reduce the impact of such catastrophic failures and errors.

Patients and methods

Clinical settings

This study was based at the Pietermaritzburg Metropolitan Surgical Service (PMSS) at Grey's Hospital, South Africa. It is one of the largest academic hospitals in the western KwaZulu Natal (KZN) province and is one of the teaching hospitals of the University of KwaZulu Natal outside Durban. It provides undergraduate and postgraduate training for general surgery as well as subspecialist fellowship training for both local and international doctors. The PMSS covers a total catchment population of over 4.5 million. Ethics for this study was approved by the Biomedical Research Ethics Committee (BREC) at the University of KwaZulu Natal (BREC 076/18 as a substudy of BCA221/13).

The study

This study was based on data from the Hybrid Electronic Medical Registry (HEMR), which has been previously described in the literature [5]. Each patient is electronically admitted onto HEMR upon hospital admission and similarly discharged on HEMR upon hospital discharge. Within the HEMR is a module which allows for capturing of all surgical morbidities. These are entered either at the time of identification of the morbidity, retrospectively after discussion at weekly departmental morbidity and mortality meetings, or by HEMR caretakers when identified by them. All morbidities entered into HEMR from its inception in December 2012 to December 2017 were retrieved and analyzed. Those that possibly constituted never events or near misses were extracted and further examined. Where necessary, hospital records were accessed to complete missing data or provide clarity. Morbidities were then classified as 'never events,' 'near misses,' or 'not reportable.'

Results

Over the 5-year period, a total of 20,432 individual patient admissions were captured on HEMR and total of 7187 morbidities were recorded. Of these morbidities, 61.6% were in males and 38.3% in females. Patients admitted to general surgery accounted for 62.7% of the total, and trauma surgery and pediatric surgery accounted for 33.6% and 3.8%, respectively, of the total number of morbidities. Of these 7187 morbidities, a total of 79 (1.1%) never events were identified: 53 (67.1%) in males and 26 (32.9%) in females. Among the 79 never events, general surgery patients accounted for 47 (59.5%), trauma surgery for 25 (31.6%), and pediatric surgery 7 (8.9%). These never events are tabulated in Table 1. In addition to these 79 never events, a total of 126 (1.7%) near misses were identified, of which 80 (63.5%) occurred in males and the remaining 46 (36.5%) in females. General surgery patients accounted for 72 (57.1%) and trauma surgery for 54 (42.9%). No near misses were reported in pediatric surgery patients. Table 2 details the near misses. The rate of never events for all admissions was (79 never events/20,432 admissions) or 0.39%.

Pressure sores

A total of 70 pressure sores developed in our institution. Of those, 18 (25.7%) were grade 3 or 4, and therefore

Table 1 Total never events summarized by category

Never event	Number	Percent (%)
Pressure sore	18	22.8
Drug related	13	16.5
Imaging/bloods not reviewed	11	13.9
Fire/burn	7	8.9
Wrong procedure/patient/side	7	8.0
Miscellaneous	6	7.6
Loss of specimen	5	6.3
Retained swab/instrument	4	5.1
Fall	3	3.8
Fictitious vitals	2	2.5
Loss of intravascular device	2	2.5
Transfusion reaction	1	1.3
Total	79	100.0

Table 2 Near misses summarized by category

Near miss	Number	Percent (%)
Pressure sore	40	31.7
Drug related	24	19.0
Wrong patient	19	15.1
Imaging/bloods not reviewed	17	13.5
Transfusion reaction	11	8.7
Fall/jump	9	7.1
Miscellaneous	5	4.0
Wrong procedure	1	0.8
Total	126	100.0

classified as never events, while 40 (57.1%) were grade 1 or 2 and hence classified as near misses and 12 (17.1%) could not be classified owing to incomplete documentation. Pressure sores that developed at other institutions were excluded.

Drug-related morbidity

A total of 37 drug-related morbidities were recorded. Of those, 13(35.14%) constituted never events and 24 (64.86%) were near misses. Errors in prescribing accounted for 25 (67.57%) of the 37, while errors in administration occurred in 8 (21.62%). Four (10.8%) patients were given drugs to which they reported an allergy; however, none of them exhibited any signs of allergy, and in three of the four (75%), the error was only detected after several doses had been administered.

Transfusion reactions

In total, 11 transfusion reactions were reported. One file could not be found, and so no further details are known. Of the remainder, one (10%) resulted in anaphylaxis with cardiopulmonary collapse and is a never event. The other nine (90%) did not result in any appreciable serious consequence and were mostly *suspected* transfusion reactions based on the development of pyrexia during transfusion. None required any intervention beyond aborting the transfusion and are thus near misses.

Wrong patient

A total of 21 'wrong patient' episodes were documented of which 2 (9.52%) were never events and 19 (90.48%) near misses. One patient had a central venous catheter inserted when it was due to be inserted in another patient with a similar name in the same ward. This is a never event. The other never event was in a patient who had another patient's blood results placed in his file. These indicated resolution of an acute kidney injury, and intravenous fluid therapy was thus halted. This resulted in a gross deterioration of the patient's renal biomarkers. Of the 19 near misses, one occurred when the wrong patient was taken to the operating room for an elective mastectomy. The error was noted by receiving staff in the operating complex. The remaining 18 near misses comprise blood results or prescription charts being in the wrong patients' files. None of these patients experienced any direct harm.

Wrong side

One patient had an intercostal chest drain inserted on the opposite side to the pathology.

Wrong procedure

There were five incidents of the wrong procedure being performed. One patient was consented for an endoscopic percutaneous gastrostomy insertion, but the operating surgeon performed an open gastrostomy. Three patients, all in pediatric surgery, underwent bilateral inguinal herniotomies, but only had unilateral hernias. This was due to inaccurate preoperative assessment. A patient was scheduled for an open tracheostomy, but on assessment in the operating room was noted to have an esophageal ET tube, and the proposed procedure canceled. He was successfully extubated and required no further airway management.

Falls

Eleven patients sustained falls while in hospital, and one patient attempted suicide by jumping out of an unsecured window. Of the two never events pertaining to falls, one patient demised owing to an intracranial bleed as a result of the fall in the bathroom. The patient who jumped out of a window sustained multiple cervical spine and lower limb fractures and developed paraplegia. He demised in ICU due to a ventilator-associated pneumonia. This is a never event. Nine patients (75%) were documented to have fallen while in hospital care, although sustained either minor or no injuries.

Fire

Three fires and four unintentional burns were reported. All three fires resulted from diathermy use near incompletely dried chlorhexidine cleaning solution. Two fires occurred during emergency surgery. All three patients sustained superficial burns that required no further operative intervention. All four burns occurred during elective surgery. Three (75%) were unintentional burns with the diathermy point to skin other than that within the operative field. One burn occurred due to the diathermy hand-piece wire being wrapped around a towel clip in which skin had been inadvertently caught. This burn was debrided and healed without a skin graft.

Imaging/bloods not reviewed

A total of 28 morbidities were recorded where blood or imaging results were not followed up on. Of these, 11 constituted never events as there were serious consequences. These include unmanaged pneumothoraces with respiratory and/or cardiovascular compromise and severe electrolyte disturbances requiring urgent management. Seventeen were classified as near misses, because despite the similar conditions being missed there was no documented major consequence for the patient.

Retained swabs

A total of four events pertaining to retained swabs were documented. Three (75%) occurred during trauma laparotomies for abdominal gunshot wounds. One was noted on follow-up X-ray in the same admission and removed. Two occurred during damage control laparotomies; in both instances, the retained swabs were noted at the planned relaparotomies and removed without event. The fourth (25%) swab was retained during elective reversal of an ileostomy.

Loss of specimen

A total of five specimens were lost or damaged. Three were mastectomy specimens placed in water/saline and not formalin, resulting in tissue degradation beyond use by the time of histopathological examination. All three were of breast malignancies, and all occurred on a single operating list. One occurred when an intraperitoneal lymph node biopsy was discarded. This was only recognized when the abdomen was closed. One event was documented in a patient who underwent a sigmoid colectomy for a sigmoid neoplasm; this specimen was never found.

Fictitious vital signs

Two instances of vitals charts having been completed several hours prior to the claimed time were documented. Both occurred after hours and were noted by doctors reviewing the patients.

Miscellaneous never events

A number of miscellaneous never events were documented. These are not easy to classify and are listed below: A patient drank his abdominal drain fluid, a hemodynamically unstable patient was being expedited to the operating room and got stuck in a broken lift, a patient with a ‘malignant histology’ result was subjected to three cycles of chemotherapy, prior to the result being amended to ‘benign’ one, a patient stepped on a scalpel blade that had not been properly disposed of and required post exposure HIV prophylaxis, a patient developed an anaphylactic reaction to IV contrast due to not receiving steroid prep despite reporting the allergy on admission, and a patient absconded and could not be contacted.

Discussion

There is a growing realization that healthcare-related morbidity results in a major burden of disease and expense and as such must be considered a major public health problem. In addition, it seems that human error may have a significant role to play in creating this morbidity. This was first recognized at the turn of the millennium, and the monograph ‘To err is human’ is a seminal publication in this field [1]. In this report, there were seven thousand morbidities and twenty thousand patient admissions. This implies that each patient has a thirty percent chance of experiencing an adverse event while in hospital and is much higher than similar events reported in the USA, where a thirteen percent chance is quoted [6]. Never events are so egregious that they are supposed to not ever happen.

Our rate of never event is low (0.39%), and this is very much in keeping with the literature. Regardless, for the patient who experiences a never event, the consequences are major, and for the institution, the medicolegal implications are significant.

Although no healthcare system is entirely immune from error, never events can be prevented. One of the many challenges in the developing world is the lack of reporting mechanism. This is in part related to the lack of resources, and capturing these events, analyzing them, and creating systems to minimize the adverse outcome and guard against future events are particularly problematic and are left at the discretion of the individual unit or institution. This is stark contrast with well-resourced healthcare system such as the NHS where a mature system of mandatory reporting via NPSA is required. They also function to increase awareness of these events and clearly defined national standards of care. In 2014, the NHS Never Events task force reported that the three pillars of any program to reduce and eliminate surgical never events were: the standardization of generic operating department procedures, systematic education and training, and harmonizing activities designed to support and facilitate patient safety. No such task force exists in South Africa, and all attempts to promote patient safety have tended to be very localized.

In South Africa, there is no formal reporting system for morbidity in general and for never events in particular. In the UK, there is a nationwide system designed to collate information on all never events and to investigate them. The HEMR in Pietermaritzburg is a unique system and is not replicated in other institutions in the country. It is unclear whether our robust system of capturing and reporting on morbidity is followed elsewhere in the province or in the country as a whole. This needs to change, as morbidity needs to seen as a public health problem and tackled with a systematic approach. The Department of Health is struggling to deal with ongoing financial demands placed on it due to medicolegal cases, and developing a comprehensive strategy to tackle surgical morbidity is needed.

The commonest never events are grade III and IV pressure sores. Pressure care in surgical patients is hindered by postoperative pain, severity of injury, and its associated interruption of mobilization, as well as preexisting comorbid illness. Pressure point care is further weakened by diminished staff numbers and requires ongoing emphasis and supervision from nursing management and physiotherapy. Measures to prevent pressure sores are costly and demand significant ‘man-hours’ to be effective; however, the cost of managing a pressure sore is significantly higher than its prevention [7]. The next commonest are drug-related morbidities. Once again these lend themselves to formal tick box systems and to electronic ordering systems. As electronic ordering becomes more widespread, it is hoped that the incidence of drug-related never events will decrease. Failure to follow-up on investigations also reflects poor systems. As electronic and web-based reporting systems become more common, so it will be easier to alert staff when investigations are completed and if they are abnormal. Fires and burns in the operating room are an ever-present risk and ongoing education and training is needed to reduce the incidence of such an injury. In our study, all incidents were related to the use of high-energy electrosurgical devices, a trend similar to that reported in the literature [8]. Wrong surgery is particularly devastating, yet surgeons that operate on bilateral structures are estimated to have 25% lifetime risk of experiencing a wrong-site event [9]. Preoperative marking and operative checklists have been demonstrated to reduce this significantly [10].

Preventing or reducing never events requires a multifaceted strategy which promotes a culture of patient safety. This is an ongoing task for any institution, and it requires leadership to emphasize the issue and to support systems designed to promote patient safety. These systems must include a mechanism to capture morbidity, as has been done with the HEMR, as well as creating a platform to discuss and reflect on morbidity. This requires an active morbidity conference which should be held on a regular basis and be cross-disciplinary. We have set such a system up at our institution. The HEMR captures morbidity and then feeds this information into our weekly morbidity conference. Strategies to prevent never events must include the checklist approach which ensures that handovers are structured and that patients are correctly identified prior to undergoing a procedure. Surgical site marking is a useful strategy and one which we plan on introducing to our service to strengthen our existing systems.

Conclusion

Surgical morbidity is common and has a substantial impact of both the individual patient and society as a whole. Robust reporting mechanisms are needed to capture data, and these data must feed into evidence-based strategies to reduce the incidence and impact of this morbidity. Our systems ensure that our incidence of surgical never events is relatively low, but ongoing efforts must be made to ensure that we drive this level down even further.

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