

SPECIAL ARTICLE

PATIENT SAFETY

Risk Factors for Retained Instruments and Sponges after Surgery

Atul A. Gawande, M.D., M.P.H., David M. Studdert, LL.B., Sc.D., M.P.H.,
E. John Orav, Ph.D., Troyen A. Brennan, M.D., J.D., M.P.H.,
and Michael J. Zinner, M.D.

ABSTRACT

BACKGROUND

Risk factors for medical errors remain poorly understood. We performed a case-control study of retained foreign bodies in surgical patients in order to identify risk factors for this type of error.

METHODS

We reviewed the medical records associated with all claims or incident reports of a retained surgical sponge or instrument filed between 1985 and 2001 with a large malpractice insurer representing one third of the physicians in Massachusetts. For each case, we identified an average of four randomly selected controls who underwent the same type of operation during the same six-month period.

RESULTS

Our study included 54 patients with a total of 61 retained foreign bodies (of which 69 percent were sponges and 31 percent instruments) and 235 control patients. Thirty-seven of the patients with retained foreign bodies (69 percent) required reoperation, and one died. Patients with retained foreign bodies were more likely than controls to have had emergency surgery (33 percent vs. 7 percent, $P < 0.001$) or an unexpected change in surgical procedure (34 percent vs. 9 percent, $P < 0.001$). Patients with retained foreign bodies also had a higher mean body-mass index and were less likely to have had counts of sponges and instruments performed. In multivariate analysis, factors associated with a significantly increased risk of retention of a foreign body were emergency surgery (risk ratio, 8.8 [95 percent confidence interval, 2.4 to 31.9]), unplanned change in the operation (risk ratio, 4.1 [95 percent confidence interval, 1.4 to 12.4]), and body-mass index (risk ratio for each one-unit increment, 1.1 [95 percent confidence interval, 1.0 to 1.2]).

CONCLUSIONS

The risk of retention of a foreign body after surgery significantly increases in emergencies, with unplanned changes in procedure, and with higher body-mass index. Case-control analysis of medical-malpractice claims may identify and quantify risk factors for specific types of errors.

From the Departments of Surgery (A.A.G., M.J.Z.) and Medicine (E.J.O., T.A.B.), Brigham and Women's Hospital; and the Department of Health Policy and Management, Harvard School of Public Health (A.A.G., D.M.S., T.A.B.) — both in Boston. Address reprint requests to Dr. Gawande at the Department of Surgery, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115.

N Engl J Med 2003;348:229-35.

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ERROR IN MEDICINE IS COMMON AND may cause harm.¹ However, isolating the factors underlying specific types of errors has proved to be a formidable task. The types of errors that occur vary widely because of the extreme complexity and heterogeneity of the tasks involved in medical care. Furthermore, many of the most devastating errors happen too infrequently for observational or single-institution studies to identify the risk factors and patterns of causation. As a result, studies of error to date have generally measured only the frequency and outcomes of specific types of errors, not the roles of particular contributing factors.

One persistent but poorly understood error is leaving sponges or instruments inside patients who undergo surgery. Such incidents may result in major injury. In a report on 24 cases of foreign bodies retained after intraabdominal surgery, complications observed included perforation of the bowel, sepsis, and in two patients, death.² The retention of sponges and instruments is considered by many to be avoidable, and when it occurs, it can attract wide, critical press coverage.³⁻⁵ Yet these errors persist. Although the incidence has not been determined, estimates suggest that such errors occur in 1 of every 1000 to 1500 intraabdominal operations.^{6,7}

There is great uncertainty about why these incidents occur and how to prevent them. The standards of the Association of Operating Room Nurses have long required that only sponges detectable on radiography be used and that they be counted once at the start and twice at the conclusion of all surgical procedures.⁸ The standards also recommend that instruments be counted in all cases involving an open cavity. If a count is incorrect — that is, not all materials are accounted for — then radiography or manual reexploration is to be performed. In published case series, some incidents appear to result from a failure to adhere to these standards.^{9,10} However, in the majority of cases, foreign bodies go undetected despite proper procedures. Previous descriptive studies have been unable to establish the human and systems-related factors involved.¹⁰

We performed a case-control study to identify risk factors for the retention of foreign bodies during surgery that might provide direction for ameliorative efforts. Because these cases are avoidable and frequently injurious, many lead to malpractice claims; given the high likelihood of litigation after such cases, most liability insurers also encourage clinicians and hospitals to report them. Therefore, we used malpractice-insurance files from several institutions to identify cases.

METHODS

CASES AND CONTROLS

We used a retrospective case-control design. Patients with cases were those in whom instruments or sponges had been left after a surgical procedure; controls were patients who had undergone the same type of procedure without this complication.

To obtain cases, we sought records from all malpractice claims and incident reports involving retention of a surgical instrument or sponge that were filed between January 1, 1985, and January 1, 2001, with the Controlled Risk Insurance Company (CRICO), a malpractice insurer representing one third of the physicians in Massachusetts and 22 hospitals. We first performed a computerized search of CRICO's administrative data base to identify potential cases. Then, a physician-reviewer screened the legal and medical records associated with these cases to select those in which records confirmed that a surgical instrument or sponge was inadvertently left in the patient after a surgical procedure and in which operative records were available for review.

For each case, we identified a set of control patients from among those who had undergone the same procedure as a given patient with a retained foreign body during the same period at, when feasible, the same institution. Given an estimated 60 cases available for review, we determined that four controls for each case would give the study sufficient power to detect a risk factor present in 30 percent of patients that produced a doubling of the likelihood that a foreign body would be left behind. Through a search of hospitals' administrative data bases, we identified at least 10 patients who had undergone the same principal procedure, as defined according to the procedure codes of the *International Classification of Diseases, 9th Revision, Clinical Modification*¹¹ during the six-month period preceding the date of surgery in the corresponding case. We then randomly selected five patients for a review of records (one more than the minimum, because we anticipated that some might not have complete records available).

The cases came from 10 hospitals, with 4 hospitals accounting for 83 percent of the cases. We were able to obtain permission to sample controls from these four principal hospitals only. For cases from the remaining six hospitals, we selected matching controls from the principal hospitals in proportion to their share of cases. We obtained approval for the review of records from the institutional review board at each of the four hospitals, and we obtained

approval for the overall study from the institutional review board at Brigham and Women's Hospital, Boston.

DEVELOPMENT OF THE DATA FORM

We developed a data form for recording information about patients with a retained foreign body and controls on the basis of a review of the literature and interviews with individual surgeons. Possible risk factors identified in the literature were a change in nursing personnel during surgery, excessive loss of blood, lack of a complete count of sponges and instruments, fatigue in the surgical team due to the lengthiness or lateness of the procedure, and urgency of the surgery.^{7,9,10} The surgeons we interviewed cited the following additional factors, drawn from anecdotal experience: obesity of the patient, unexpected intraoperative developments, the involvement in a procedure of multiple surgical teams, and the performance of more than one major procedure at a time.

The final form included the following information: age; sex; weight and height; the cavity of operation; the starting time; the duration of the operation; the volume of blood lost; the volume of blood transfused; whether the operation was performed on an emergency basis; whether unexpected developments led to a change in or addition to the procedure that had been planned; whether more than one surgical team, more than one major procedure, or both were involved; whether there was a complete count of sponges and instruments; whether the nursing personnel changed between counts; and whether the surgeon or another team member (a resident or physician's assistant) performed the closure. Operations starting between 5 p.m. and 7 a.m. or completed between 7 p.m. and 7 a.m. were categorized as late procedures. The operation was classified as an emergency (needed to be performed within hours), urgent (needed to be performed within hours to days), or elective. Emergency surgery included repair of a symptomatic aortic aneurysm, operation for trauma, unplanned cesarean section, hysterectomy for uncontrolled postpartum bleeding, and closure of vaginal or rectal tears after delivery. Cases involving unexpected changes in procedure included those with unanticipated findings of a perforated diverticulitis, ectopic pregnancy, duodenal mass, or other new diagnoses, as well as technical complications including bladder laceration requiring repair, shoulder dystocia at delivery, and intraoperative respiratory failure. For patients

with a retained foreign body, we also recorded the type of foreign body retained, the way in which it was detected and when it was detected, the corrective procedure (if any), and the patient's health outcome.

RECORD REVIEW

Four senior surgical residents who were trained to use the data form conducted reviews of records during the fall of 2001. In addition, we extracted data on indemnity payments and legal-defense expenses for the cases from the insurer's administrative data base.

STATISTICAL ANALYSIS

We generated descriptive statistics and performed a matched case-control analysis using univariate conditional logistic regression. Variables found to be associated with an increased likelihood of retention of a foreign body in univariate analysis at a level of statistical significance of $P < 0.20$ were then included in a multivariate conditional logistic-regression model. Because retention of objects occurs relatively rarely, odds ratios were considered to approximate risk ratios. We performed all analyses using the SAS statistical package, version 8 (SAS Institute).

RESULTS

CHARACTERISTICS OF THE CASES

We identified 60 potential cases in CRICO's administrative data base. Fifty-four were confirmed to involve a retained foreign body after surgery and to have the required medical records available. Forty-seven of these cases were identified on the basis of malpractice claims and seven on the basis of incident reports.

These cases involved 61 retained foreign bodies. A total of 69 percent of cases involved sponges; 31 percent involved instruments (Table 1). No major bodily cavity was spared. Over half (54 percent) of the foreign bodies were left in the abdomen or pelvis, 22 percent in the vagina, 7.4 percent in the thorax, and 17 percent elsewhere, including the spinal canal, face, brain, and extremities. No surgeon was responsible for more than one case.

The median date of detection was the 21st day after surgery (range, day of surgery to 6.5 years after surgery). In only 3 of 54 cases (6 percent) was the retained object detected by the first day after surgery. In 14 cases (26 percent), the retained object was not

Table 1. Characteristics of 54 Cases of a Retained Foreign Body after Surgery.

Characteristic	No. of Cases (%)
Type of foreign body retained	
Sponge	37 (69)
>1 Sponge	4 (7)
Clamp	4 (7)
Other (e.g., retractor or electrode)	13 (24)
Cavity in which foreign body was left	
Abdomen or pelvis	29 (54)
Vagina	12 (22)
Thorax	4 (7)
Other	9 (17)
Outcomes	
Death	1 (2)
Readmission to hospital or prolonged hospital stay	32 (59)
Sepsis or infection	23 (43)
Reoperation	37 (69)
Fistula or small-bowel obstruction	8 (15)
Visceral perforation	4 (7)

detected until 60 days or more after surgery. The objects were most often detected by radiography or computed tomography (67 percent). Other retained objects (24 percent) were detected on physical examination or self-examination (particularly for objects left behind after vaginal procedures) or on reoperation (9 percent).

Overall, the retention of a foreign body was a rare event. The incidence varied from 1 in 8801 to 1 in 18,760 inpatient operations at the nonspecialty acute care hospitals (the four principal hospitals and one other) insured by CRICO for which complete data on inpatient operations and claims and incident reports on retained foreign bodies were available throughout the period from 1990 through 2000. However, the consequences were serious. Thirty-seven patients with a retained foreign body (69 percent) required reoperation for removal of the object and management of complications. In the remainder, the foreign body was expelled, could be removed at the bedside, or was discovered incidentally and removed at the time of another operation. In 12 cases (22 percent), the retained foreign bodies resulted in small-bowel fistulae, obstruction, or visceral perforations; and in 1 case, the retained object resulted in death.

In all 47 of the cases that had prompted litigation, the claims were closed by the time of our review. These claims resulted in an average of \$52,581 in costs for compensation and legal-defense expenses.

CASE-CONTROL ANALYSIS

We obtained complete medical records for 235 controls (a mean of 4.4 per case). According to univariate analyses, cases were more likely to involve an emergency surgical procedure, an unexpected change in procedure, a procedure involving more than one surgical team, or the lack of a count of sponges and instruments (Table 2). Of the patients with a retained foreign body, 33 percent had undergone an emergency operation, whereas only 7 percent of the control patients had undergone such an operation. A total of 34 percent of patients with a retained foreign body had undergone an operation with an unexpected change in procedure, as compared with 9 percent of control patients (Table 2). Patients with retained foreign bodies also had a significantly higher body-mass index than control patients. The age of the patient, the duration or lateness of the operation, and the involvement of multiple procedures were not significantly associated with a risk of retention of a foreign body. Among the instances in which counts were performed, the count was reported as correct for 88 percent of patients with retained objects and 92 percent of controls; the difference between groups was not significant.

In multivariate analysis (Table 3), three factors remained significantly associated with an increased risk of retention of a foreign body: emergency procedure (risk ratio, 8.8; $P < 0.001$); unplanned change in the procedure performed (risk ratio, 4.1; $P = 0.01$); and body-mass index (risk ratio for each one-unit increment, 1.1; $P = 0.01$). The sex of the patient, the involvement of multiple teams, the estimated volume of blood lost, and changes in nursing personnel were not significantly associated with the risk of retention of a foreign body. Failure to perform a count of the sponges and instruments, which had shown a strong relation to the retention of foreign bodies in univariate analysis, was no longer a significant predictor in the multivariate model. Further testing showed that omission of counts was strongly related to the emergency status of the procedure.

DISCUSSION

Our study confirms previous findings that the leaving behind of foreign bodies in a patient after surgery is an uncommon but dangerous error. The incidence we found of 1 in 8801 to 1 in 18,760 inpatient operations corresponds to one case or more

Table 2. Characteristics of Patients with a Retained Foreign Body, Control Patients, and Procedures.*

Characteristic	Patients with a Retained Foreign Body (N=54)	Control Patients (N=235)	P Value
Age — yr	46.3±17.6	48.3±18.5	0.39
Female sex — no./total no. (%)	34/54 (63.0)	161/235 (68.5)	0.19
Body-mass index†	28.2±6.3	26.4±5.2	0.04
Counts of sponges and instruments performed — no./total no. (%)	36/54 (66.7)	181/228 (79.4)	0.01
Count considered correct	30/34 (88.2)	167/181 (92.3)	0.44
Duration of operation — min‡	181.9±152.7	173.8±152.1	0.20
Estimated volume of blood lost — ml§	771.9±1646.5	503.8±982.6	0.06
Blood loss of >500 ml or transfusion given — no./total no. (%)	21/53 (39.6)	72/212 (34.0)	0.43
Operation performed on emergency basis — no./total no. (%)	18/54 (33.3)	16/235 (6.8)	< 0.001
Operation performed after hours — no./total no. (%)¶	15/46 (32.6)	57/232 (24.6)	0.26
Unexpected change in operation — no./total no. (%)	18/53 (34.0)	21/235 (8.9)	< 0.001
>1 Surgical team involved — no./total no. (%)	8/54 (14.8)	17/235 (7.2)	0.05
>1 Major procedure performed — no./total no. (%)	9/54 (16.7)	27/235 (11.5)	0.31
Change in nursing staff during procedure — no./total no. (%)	19/33 (57.6)	76/177 (42.9)	0.16
Surgeon present at closure — no./total no. (%)	30/44 (68.2)	112/181 (61.9)	0.80

* Plus-minus values are means ±SD. Denominators are the number of patients with data on the given variable. P values were determined by matched univariate logistic regression.

† The body-mass index is the weight in kilograms divided by the square of the height in meters. Data were missing for seven patients with retained foreign bodies and five control patients.

‡ Data were missing for four patients with retained foreign bodies and one control patient.

§ Data were missing for 9 patients with retained foreign bodies and 31 control patients.

¶ Data are for operations that were started between 5 p.m. and 7 a.m. or completed between 7 p.m. and 7 a.m.

each year for a typical large hospital. Because these rates are calculated only on the basis of malpractice claims, they are most likely underestimates. Also, because of the lack of procedure-specific data, the operations that form the denominator for our calculation of incidence include large numbers of laparoscopic, endoscopic, or catheterization procedures — interventions that are unlikely to result in a forgotten instrument or sponge. (We found no cases involving such procedures.) The rates are most likely substantially higher for operations involving an open cavity. Overall, our results suggest that, given the 28.4 million inpatient operations performed nationwide in 1999,¹² more than 1500 cases of a retained foreign body occur annually in the United States.

The case-control method we applied identified several risk factors for these complications. We found that the retention of a foreign object was nine times as likely when an operation was per-

formed on an emergency basis and four times as likely when an operation involved an unexpected change in procedure. Each of these factors marks situations in which disorganization is increased so that it becomes more difficult to keep track of materials. One indication of this relation is our finding that emergency operations were significantly more likely to involve a failure to perform a count of sponges and instruments. The increased risk associated with increased body-mass index probably reflects the amount of room there is in a patient in which to lose a sponge or instrument.

Certain limitations must be considered in interpreting the findings of our study and the value of its methodology for research on other domains of patient safety. Malpractice claims and reports are an imperfect representation of the true incidence and nature of any complication.¹³⁻¹⁵ Some cases of retained foreign bodies undoubtedly did not result in either a claim by a patient or a report by the physi-

Table 3. Risk Factors for Retention of a Foreign Body after Surgery.*

Characteristic	Risk Ratio (95% CI)	P Value
Operation performed on an emergency basis	8.8 (2.4–31.9)	<0.001
Unexpected change in operation	4.1 (1.4–12.4)	0.01
>1 Surgical team involved	3.4 (0.8–14.1)	0.10
Change in nursing staff during procedure	1.9 (0.7–5.4)	0.24
Body-mass index (per 1-unit increment)	1.1 (1.0–1.2)	0.01
Estimated volume of blood lost (per 100-ml increment)	1.0 (1.0–1.0)	0.19
Counts of sponges and instruments performed	0.6 (0.03–13.9)	0.76
Female sex	0.4 (0.1–1.3)	0.13

* Characteristics with P values of less than 0.05 according to matched multivariate logistic regression were considered to be associated with a significantly increased risk of retention of a foreign body. CI denotes confidence interval.

cian to the insurer. The factors involved in such cases may differ from those in the cases we studied. However, we know of no reason why they would differ in terms of the mechanism of causation. In addition, these mishaps appear to have a high likelihood of leading to litigation, given how injurious and potentially avoidable they are.

Our results suggest at least two possible measures to reduce the occurrence of retention of foreign bodies. Although counts of sponges and instruments were performed in most cases, there was no documentation of such a count one third of the time. The observation that the failure to perform these counts was not a significant risk factor according to multivariate analysis does not imply that such counts are not important. Rather, the emergency nature of an operation or the involvement of an unexpected change in procedure was a marker of increased risk from potentially several mechanisms, of which failure to perform counts was apparently just one. We found that counts of sponges were universally omitted after the closure of an episiotomy or vaginal tears after delivery; 11 such procedures involved retained sponges. We strongly recommend that hospitals actively monitor compliance with the existing standard of counting sponges in every operation, including obstetrical procedures, and

of counting instruments in every operation involving an open cavity.

Counts are clearly not always sufficient, however. Of the many cases of retained foreign bodies in which counts were performed, 88 percent involved a final count that was erroneously thought to be correct. These findings suggest that screening of high-risk patients at the end of operations should be considered even when counts are documented as correct. The primary method currently available is radiographic screening, ideally performed before the patient leaves the operating room. The current use of radiographic screening varies widely. A few institutions obtain radiographs in every patient who undergoes an open-cavity operation; most use radiography only in those with a count that is recorded as incorrect; some appear to have no policy regarding radiography at all.¹⁶

Our findings imply that routine intraoperative radiographic screening in selected, high-risk categories of operations could prove to be a useful measure for detecting foreign bodies that have been inadvertently left behind. On the basis of previous estimates that such incidents occur in 1 in 1500 operations involving an open abdomen or chest⁶ and our findings that emergency status applied to one third of patients with retained objects and just 7 percent of controls, we estimate that 300 radiographs would be needed to detect 1 retained foreign body. A prospective study would be needed to test such an estimate. However, given costs of more than \$50,000 per case for malpractice-claims expenses alone, a \$100 plain film could prove a cost-effective intervention.

Policymakers have advocated establishing reporting systems for errors to obtain information on the patterns underlying specific types of errors.¹ Our study presents an effective method for identifying and quantifying risk factors for medical errors from such data, even for types of errors that are relatively rare.

Supported by a grant (U18HS11886) from the Agency for Healthcare Research and Quality and by the Risk Management Foundation of the Harvard Medical Institutions. Dr. Studdert was also supported in part by a grant (KO2HS11285) from the Agency for Healthcare Research and Quality.

We are indebted to Kathy Dwyer and Anthony Chamberas for assistance with data acquisition; to the hospitals and staff members who provided access to the medical records required for this study; and to Elisabeth Burdick for assistance with data management.

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