INTRAOPERATIVE RADIOGRAPHIC DETECTION OF RETAINED SURGICAL SPONGES

OBJECTIVE

The aim of this prospective study is determine the efficacy of intraoperative x-ray to rule out retained surgical sponges.

BACKGROUND

Retained surgical sponges can be result in serious medical morbidities such as infection, pain, abscess and contribute to medicolegal problems. In a retrospective control study with nearly two hundred thousand surgeries, the retained foreign object rate was found approximately 1/5500 [Cima 2008]. Sponges were the most common items left behind [Lincourt 2007]. Even though there are strict protocols to account for every surgical sponge used during a procedure, human error is not zero. When a retained surgical sponge is suspected, intraoperative x-ray images can be obtained to rule out a foreign body [Turgut 2018]. One radiographic image of the surgical field is most commonly preferred. However, a retained surgical sponge may not appear on intraoperative x-rays. The aim of this study is to determine how sensitive and specific x-rays are for detecting retained surgical sponges. Another aim of this study is determine if two views of the surgical field improve detection of retained sponges and may decrease false negative rates.

METHODS

Study Design

This is a prospective, randomized study with two cohorts: one experimental and one control. Anteroposterior (AP) and lateral (LAT) radiographs are routinely obtained as standard of care during spine surgery to confirm proper implant placement. These images will be used in this study. In one-half of the study subjects, a surgical sponge will be intentionally placed in the surgical field prior to imaging. Postoperatively, three spine surgeons (Fellows of Twin Cities Spine Center) who did not participate in the surgery will assess the images for the presence or absence of a retained surgical sponge.

Sample Size

Our hypothesis for statistical analysis is that there will be 90% sensitivity/specificity [Revesz 1983]. For a 95% confidence interval with p=0.05, a sample size of n=146 is estimated [Jones 2003].

Subject Consent

The PI will identify a potential subject based upon the recommended surgical treatment. Preoperatively on the day of surgery, the PI will explain the study to the patient and ask if he/she would be interested in participating. If the patient is interested in participating, TCSC research staff will consent the patient. Consenting will occur privately in the Preoperative Care Center (POCC).

Inclusion Criteria

- Patients undergoing open posterior instrumented lumbar spine surgery.
- Read and understand English.

Exclusion Criteria

- Pregnancy.
- Patients who do not consent to research.
- Patients less than 18 years old at the time of consent.
- Do not read and understand English.

Blinding

This will be a semi-blinded trial. Investigators performing the surgery will know whether or not a sponge is present but the investigators reviewing the images will not. Subjects will not be told which study group they are in.

Randomization

Randomization will be performed prior to surgery using sealed envelopes. One hundred forty six (146) envelopes will be sequentially numbered and 146 chits with either the number “1 (retained sponge, n=73) or the number “2” (no retained sponge, n=73) will be prepared. Chits will be drawn at random and sequentially placed in the envelopes, which will be sealed. For each consented subject, when surgery is scheduled, an envelope will be opened and the surgery worksheet annotated, as appropriate.

Data Collection

Demographic information will include sex, age, height, and weight. Surgical information will

include the number of levels decompressed and instrumented, type and configuration of instrumentation, use of bone graft and/or biologics, estimated blood loss, and length of surgery. Radiographic images will include AP and LAT views of the surgical field prior to closing.

Methods

For subjects in study group 1, the following will happen:

- OR staff will count surgical sponges, as is routine.
- AP and Lateral radiographic images will be taken of the surgical field. (This is Standard of Care, because radiographic images are taken for all patients to confirm correct placement of the instrumentation.
- Just prior to imaging, the surgeon will purposely place a sponge in the wound. He will state this to the circulating nurse and scrub tech.
- After imaging, the surgeon will remove the sponge. He will state that he has removed the sponge; the scrub tech will confirm that the sponge has been removed; the circulating nurse will note this in your chart.
- OR staff will re-count surgical sponges to be certain none are left in the wound.

For subjects in study group 2, the following will happen:

- Two radiographs will be taken of the spine (AP and Lateral views) to verify that the instrumentation is placed properly.
- OR staff will re-count surgical sponges to be certain none are left in the wound.

For all subjects:

Images will be stored on Allina's medical record system. Three investigators (TCSC Fellows, TBD) not participating in the surgery will independently view the images and note if a retained sponge is visible on either image or both.

Statistical Methods

This study will quantify the relative specificity, sensitivity, positive and negative predictive values, and accuracy of 1) an AP image alone, 2) a LAT image alone, and 3) AP and LAT images together. The results will be analyzed to determine effects of demographic and surgical variables. The McNemar test and generalized linear mixed models will be used as statistical tools [Hellbach 2018].

RISK/SAFETY INFORMATION

This study presents no additional risk to subjects associated with the radiographs because two x-rays of the surgical field are obtained as the standard of care. If the subject is of child bearing potential, the PI will have already discussed the risks of lumbar spine surgery, which includes the use of radiographs.

A count of sponges will be performed before and after the sponge is placed in the imaging field to ensure the sponge is removed. (Counting is the standard procedure [AORN 2018].); the subjects are not at greater risk from the radiographs.

There is no additional risk to surgeons as the two radiographs are the standard of care.

STUDY OVERSIGHT

The protocol, informed consent document and relevant supporting information will submitted to the IRB for review and must be approved before the study is initiated. This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements. The study will be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and 56 [add 312 for IND studies or 812 for device studies], applicable laws and the IRB requirements. A protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided the IRB is notified within 10 working days.

It will be the responsibility of the investigator to provide each subject with full and adequate verbal and written information using the IRB-approved informed consent document, including the objective and procedures of the study and the possible risks involved before inclusion in the study. Informed consent will be obtained prior to performing any study-related procedures, including screening and changes in medications including any washout of medications. A copy of the signed informed consent will be given to the study subject.

Study data will be made available for monitoring, auditing, IRB review and regulatory inspection by providing direct access to study related source data. The study may be prematurely closed for administrative reasons by the Principal Investigator (for examples, lack of enrollment, lack of adequate research staffing, lack of adequate funding). The study

may be prematurely by the safety monitors based on study progress or adverse events.

CONFIDENTIALITY

Data will be stored on TCSC computers, which are linked by Allina Health servers. No data will be physically removed from TCSC. The United States Food and Drug Administration may inspect all records related to the study. The IRB and/or other regulatory authorities (for example, the United States Food and Drug Administration) will have access to study-related medical records. Study-related records identifying the subject will be kept confidential and, to the extent permitted by applicable laws and/or regulations will not be made publicly available. If any results of the study are published, the subject's identity will remain confidential.

INTENDED USE OF THE DATA

The study investigators may publish the results of the study in medical journals and society meetings. The study investigators may use the results to modify the Standard of Care.

STUDY FUNDING

This study is funded through the Twin Cities Spine Surgeons and Allina Health. Study procedures will occur at Twin Cities Spine Center and Allina Health facilities. Subjects will incur no costs.

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