

STUDY PROTOCOL

Study name	Topical Antibiotic Treatment for Spine Surgical Site Infection
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ABSTRACT

Surgical site infection (SSI) after spine surgery is a devastating complication. It is classified as a “never event” by payers, because it is presumed to be the result of a lapse in quality. A mainstay of SSI prevention is antibiotic treatment, but antibiotic concentrations are lower in bone tissue than blood levels. Because of this, there has been increasing interest in the use of intra-wound antibiotics (IWA) placed directly on the spine at the completion of surgery to help avoid spine SSI. However, because spine SSI happens relatively infrequently and there is considerable variation in IWA techniques among hospitals and surgeons, it remains to be determined if the broad use of IWA would actually decrease rates of spine SSI.

The goal of this study was to better understand surgeon practices and beliefs around intra-wound antibiotics. The Comparative Effectiveness Research Translation Network (CERTAIN) Spine Infection Study partnered with spine surgery clinics and hospitals to invite surgeons and staff to participate in research activities designed to characterize patterns of IWA use, identify knowledge gaps around IWA, and design further research and implementation tools to support IWA adoption as appropriate.

OBJECTIVES

Compare knowledge, beliefs and attitudes about IWA with the actual use of IWA by surgeons.

Rationale: Assessing barriers to increasing IWA use is critical to an eventual trial. Commonly, educational gaps drive variability in practice but beliefs and attitudes may also contribute. Additionally, assessing variability in how IWA is used may reveal bias and confounding that will need to be addressed in a trial and require the addition of other surveillance metrics. To assess this, we will perform a survey of all WA State spine surgeons asking about knowledge, attitudes, and behaviors related to the use of IWA, and compare gaps in knowledge with historic IWA use patterns. We hypothesize that surgeons who use IWA more often have more knowledge about IWA than less frequent users.

DESIGN

The estimated 5-10 minute survey asked surgeons about their training, practice and knowledge, use patterns of IWA and attitudes and beliefs surrounding IWA. Specifically, the investigative team framed questions in one section about their opinion of IWA usage and a second section about their current practice patterns for using IWA. In order to avoid bias of one section always being answered first and influencing the second, these two sections of the survey were randomized so that any given participant was either given questions about their opinion of IWA use first, or questions about their current use of IWA first. In between these two sections we asked surgeons about whether they thought an RCT for IWA was needed, and if they would be willing to participate and randomize their patients.

The study team conducted a research prioritization workshop at the SCOAP Annual Conference in 2017. This exercise was to better understand what types of research and what areas of research current clinicians and hospital administrators thought were important. The prioritization exercise involved a brief survey given to attendees at a breakout session during the conference, followed by facilitated group discussion around survey results.

The goal of the second strategy was to get a more in depth understanding of the results we found in the original surgeon survey via interviews that included questions about 1) use patterns of IWA, 2) opinion of scientific evidence for IWA use, 3) its effectiveness to reduce SSI, and 4) best practices for evidence generation in clinical practice. Interviews lasted about 20-30 minutes and were conducted with a qualitative research coordinator. The interviews were split into two parts, 1) gaining a deeper understanding of IWA use, scientific evidence, and evidence generation in surgical practice, and 2) review 2-3 case scenarios for how evidence could be generated for IWA use.

Participating surgeons were notified that they could skip any questions if they were uncomfortable answering and were asked if they would be willing to be recorded for data collection purposes. Interviews were then transcribed and reviewed for themes.

METHODS

Surgeons recruited from six surgical professional organizations agreed to participate in the study, including: Seattle Science Foundation ONE Spine, Washington State Orthopaedic Association, North American Spine Society, Cervical Spine Research Society, Lumbar Spine Research Society, and Surgical Clinical Outcomes Assessment Program. Within these organizations 91 surgeons participated.

INCLUSION CRITERIA:

Patients may enroll in Spine Infection if they:

- Spine surgeons completing >5 operations per year
- Practice in the United States

For more information regarding the scientific background and statistical methods, see the Statistical Analysis Plan (SAP).

LIKELY IMPACT

The results of this study will support the design and conduct of a cRCT within the Spine SCOAP-CERTAIN network and/or inform other researchers considering such a trial. Ultimately, this study should determine the effectiveness of adding IWA to standard infection prevention regimens to avoid SSI after spine surgery. Demonstrating that IWA is effective would represent a major shift in the practice of spine surgery and have direct benefits to thousands of patients each year.