

Evidence-Based Guideline: Pedicle Screws in Intraoperative Monitoring

Report of the Guidelines Committee on the American Academy of Neurology

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Appaji Rayi nothing to disclose

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ABSTRACT

Objective: We evaluated the evidence for pedicle screw stimulation in spinal cases, considering it as a therapy, to reduce the risk of medial wall rupture. We also looked for evidence of trains of stimulation, and percutaneous stimulation.

Methods: We reviewed the literature, identified relevant published studies, and classified the studies according to American Academy of Neurology criteria.

Results: There was a single Class III study which answered the question of pedicle screw stimulation. It found a positive likelihood ratio of 3.5 (95% CI 2.3-5.4] with triggered EMG.

Recommendations: For patients undergoing spinal instrumentation of the pedicles from C7-T1, pedicle screw stimulation may be considered an option to decrease risk of medial wall breach (Level C).

For patients undergoing spinal instrumentation of the pedicles, there is neither evidence for, nor against,

- 1) pedicle screw stimulation
 - 2) trains of pedicle screw stimulation,
 - 3) stimulation of percutaneous pedicle screws
- to decrease the risk of medial wall breach (all level U).

INTRODUCTION

The previous AAN guideline about intraoperative monitoring focused on intraoperative monitoring as a diagnostic test (Nuwer 2012). They found more than ten low or moderate risk of bias studies, and were able to come up with a single strong recommendation. Since they used the diagnostic classification of bias, they were unable to recommend the use of intraoperative monitoring, even though they were able to make a strong recommendation.

In light of this previous experience, we wished to look at pedicle screw stimulation not as a diagnostic test, but as a therapy. While the risk of bias is different, and, in some ways, harder to qualify for, it might, possibly allow for recommending the use of pedicle screw stimulation.

This evidence-based systematic review seeks to answer questions the following questions among patients with undergoing spinal instrumentation for surgical correction of their spinal disorder:

1. Does pedicle screw stimulation compared with routine care reduce the risk of medial pedicle breach?
2. Does pedicle screw stimulation with trains compared with typical stimulation reduce the risk of medial pedicle breach?
3. Does percutaneous pedicle screw stimulation, compared with usual care reduce the risk of medial wall breach?

In these PICO questions, we are not asking the diagnostic accuracy question; rather, we are asking, if the use of pedicle screw stimulation has a therapeutic effect. According, we classified studies using the AAN therapeutic classification. This is intentional, as writing questions which would require the use of a prognosis classification, does not answer therapeutic questions.

In order not to minimize bias from generalizability it was preplanned to separate data found into the spinal region covered by the individual papers. For example, if there is a paper covering the lumbar region and another paper covering the thoracic region, these results will be separated. Combining the two papers would require a downgrade when using the modified GRADE process.

The purpose of this guideline is to inform intraoperative monitoring practitioners, neurologists, surgeons, and patients who may be contemplating getting back surgery of the narrow question of whether there may be evidence for the use of triggered EMG in spinal as a therapy to reduce injury.

DESCRIPTION OF THE ANALYTIC PROCESS

The American Clinical Neurophysiology Society Guideline Committee convened an expert panel to develop the systematic review, of three board certified clinical neurophysiologists, one of whom could function as a methodologist (DG). We used the 2011 AAN process (AAN 2011),

with their grading system for therapeutic articles. Since the ACNS is a different organization, some explicit differences were pre-planned:

1. The reviewing committee was the guidelines committee of the ACNS,
2. Broad review was on the ACNS website,
3. Final approval was by the board of the ACNS, rather than the board of the AAN.
4. When grading a paper required a judgment call, this was to be explicitly included in the paper to provide greater transparency,
5. In the absence of any evidence above Class IV, we elected to not perform modified GRADE and modified Delphi, to possibly create a therapeutic recommendation. Recommendations created this way would essentially be consensus-based recommendations, which were not the goal of this guideline,
6. The modified Delphi process was a discussion among the three authors rather than formal voting with at least five people. Consensus was considered achieved if two authors voted the same category, and one author voted no more than one category different.

We searched Medline, CINAHL, DARE, CENTRAL databases. Please see figure one for the search used for medline. The original search was from Jan 1991 to Jan 2015, resulting in a total of 702 abstracts. Surveys, case reports/series, trials without control arms, trials which did not provide enough data to define measures of diagnostic accuracy, and Class IV (by AAN risk of bias) studies were excluded. References of full text review studies, as well as systematic reviews, were searched for additional papers which might meet inclusion criteria. Conference abstracts were hand searched for additional possible abstracts which might meet inclusion criteria. Of these abstracts, 49 were evaluated for full text review in a blinded fashion by two guideline authors. If the papers met inclusion criteria, the guideline authors graded them for risk of bias by the AAN classification. Any disagreement in classification was a priori agreed to be resolved by mutual discussion. One paper had a classification above Class IV which was presented in table 1.

ANALYSIS OF EVIDENCE

Question 1: In patients undergoing instrumentation with pedicle screws for spinal disorders, does pedicle screw stimulation compared with routine care reduce the risk of medial pedicle breach?

Analysis. We found a single Class III paper which addressed this issue (Holdefer 2013). The paper considered triggered EMG thresholds from instrumentation of 32 patients whose surgeries encompasses C3 to T1. These results were compared to CT images without reference to the EMG thresholds. We considered this adequate for purposes of blinding. The study found that a sensitivity of 5 mA or less had a sensitivity of 73% (90% CI 43-90%) and a specificity of 79% (95% CI 75-83%) for detection of an inaccurate and potentially dangerous trajectory, with corresponding LR+ of 3.5 (95% CI 2.3-5.4) and LR- 0.3 (95% CI 0.1-0.0). There were no statistically significant differences between control and pedicle screw stimulation in risk of inaccurate and potentially dangerous holes. There was a trend for decreased risk in the

subgroup of pedicles (C7-T1), but no trend was observed in the subgroup of lateral masses (C3-C8).

Conclusion. There is very low confidence in evidence that pedicle screw stimulation at C3-T1 reduces the risk of medial wall breach (one Class III study).

There is neither evidence for nor against pedicle screw stimulation at other levels (no studies above Class IV).

Modified GRADE (for pedicle screw stimulation at C3-T1 levels)

| Intervention-Outcome pair | Studies | Effect | Comment | Overall confidence in evidence |
|--|---------------|---|---|--------------------------------|
| Pedicle screw stimulation – risk of medial wall breach | One Class III | No statistically significant change in risk | Downgraded for inability to exclude a significant association | Very low |

| Precision | Consistent | Directness | Publication Bias | Plausible | Magnitude of Effect | Dose Response |
|-----------|------------|------------|------------------|-----------|---------------------|---------------|
| D | - | - | - | - | - | - |

Clinical Context. Medial wall breach is at risk for being dangerous for patients (Prin). There is a trend for decreased risk when using pedicle screw stimulation in the pedicles of C7-T1, with a LR+ of 3.5 with a positive stimulation (Evid). Patients and physicians would want to know whether they had medial wall breach or not, since there are increased risks (Infer).

Modified Delphi.

Step One: Strength of Inference.

| Strength of inference | Weak | Modest | Moderate | Strong | Consensus |
|-------------------------|------|--------|-----------|--------|-----------|
| Internal inferences | <50% | 50-80% | >80-<100% | 100% | Yes |
| Strong-related evidence | <50% | 50-80% | >80-100% | | NA-Yes |

| | | | | | |
|--------------------------|----------|--------|-----------|------|-----|
| Acceptance of principles | <50% | 50-80% | >80-<100% | 100% | Yes |
| Logical | <50% | 50-80% | >80-<100% | 100% | Yes |
| Evidentiary anchor | Very Low | Low | Moderate | High | |

Overall strength of inference: Weak.

Step Two: Strength of Recommendation

| Modifier | R/U | C | B | A | Consensus |
|--------------------------|---------------|--------------------|----------------|-----------|-----------|
| Availability | Limited | Sometimes | Usually | Universal | Yes |
| Financial burden | Prohibitive | Moderate | Minimal | None | Yes |
| Variation in preferences | Large | Moderate | Small | Minimal | Yes |
| Importance of outcome | Not important | Somewhat important | Very important | Critical | Yes |
| Benefit relative to harm | Too close | Modest | Moderate | Large | Yes |
| Strength of inference | Weak | Modest | Moderate | Strong | |

Recommendation: For patients undergoing spinal instrumentation of the pedicles from C7-T1, pedicle screw stimulation may be considered an option to decrease risk of medial wall breach (Level C).

For patients undergoing spinal instrumentation of the pedicles at other levels, there is neither evidence for, nor against pedicle screw stimulation to decrease the risk of medial wall breach (level U).

Question 2: In patients undergoing instrumentation with pedicle screws for spinal disorders, does pedicle screw stimulation with trains compared with typical stimulation reduce the risk of medial pedicle breach?

Analysis. There were no studies above Class IV which answered this question.

Conclusion. It is unknown whether single pedicle screw stimulation, compared to trains of pedicle screw stimulation, reduces the risk of medial wall breach, in patients undergoing pedicle screw instrumentation for spinal disorders (no studies above Class IV).

Recommendation. There is neither evidence for, nor against, the use of trains of pedicle screws, as a therapy, to reduce risk of medial wall breach, in patients undergoing pedicle screw instrumentation for spinal disorders (Level U).

Question 3: In patients undergoing instrumentation with pedicle screws for spinal disorders, does percutaneous pedicle screw stimulation, compared with usual care reduce the risk of medial wall breach?

Analysis. There was no evidence above Class IV to answer this question.

Conclusion. It is unknown whether percutaneous pedicle screw stimulation, compared to usual care, reduces the risk of medial wall breach, in patients undergoing pedicle screw instrumentation for spinal disorders (no studies above Class IV).

Recommendation. There is neither evidence for, nor against, the use of percutaneous pedicle screw stimulation, as a therapy, to reduce risk of medial wall breach, in patients undergoing pedicle screw instrumentation for spinal disorders (Level U).

Future Research

The key for future research in pedicle screw stimulation, like all other areas in intraoperative monitoring, is in the creation of studies which have a risk of bias below that of expert evidence.

Table One

| Paper | Number of patients | Spinal Level examined | Effects | Classification of risk of bias, questions answered |
|---------------|--------------------|-----------------------|---------|--|
| Holdefer 2013 | 32 | C3-T1 | | III, 1 |

Figure one
Medline search used:

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Search Add to builder Query Items found Time
#5 Add Search ((#1 OR #2)) AND (#3 OR #4) 702 09:18:04
#4 Add Search ((EMG) OR electromyography) OR electromyographic 81629
09:14:23
#3 Add Search Intraoperative 121322 09:12:44
#2 Add Search Pedicle screw stimulation 63 09:12:34
#1 Add Search Pedicle screw 4316 09:11:52

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