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FactFinders

FactFinders for patient safety: Preventing potential procedure-related complications: Vasovagal reactions and spinal cord stimulator lead migration

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A B S T R A C T

This series of FactFinders presents a brief summary of the evidence and outlines recommendations to improve our understanding and management of several potential procedure-related complications.

Evidence in support of the following facts is presented. (1) *Vasovagal Reactions During Interventional Pain Procedures* – The overall incidence of vasovagal reactions (VVR) ranges from 1 to 8% during interventional pain procedures, though certain patient populations may be at greater risk. Younger age, male sex, and a history of a VVR are associated with an increased likelihood of VVR. In select patients, moderate sedation may be considered for prevention of a repeat vasovagal reaction. (2) *Spinal Cord Stimulator Trial Lead Migration* – Suturing percutaneous SCS leads does not mitigate the risk of migration compared to taping alone during a trial. Most lead migration does not pose a safety concern during the trial period.

FACTFINDERS FOR PATIENT SAFETY

Vasovagal Reactions During Interventional Pain Procedures

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Fact: The overall incidence of vasovagal reactions (VVR) ranges from 1 to 8% during interventional pain procedures, though certain patient populations may be at greater risk. Younger age, male sex, and a history of a VVR are associated with an increased likelihood of VVR. In select patients, moderate sedation may be considered for prevention of a repeat vasovagal reaction.

Psychological distress or a noxious stimulus can trigger a vasovagal reaction that causes bradycardia, hypotension, and a reduction in vascular tone [1,2]. Vasovagal reactions (VVRs) typically present as dizziness, a sense of warmth or flushing, diaphoresis, nausea, blurred vision, or loss of vision. Other less common symptoms may include tinnitus, chest discomfort, weakness, yawning, or anxiety [3,4]. An extreme VVR is vasovagal syncope, in which the patient loses consciousness, usually within 2 min of onset of symptoms [5] and may even convulse.

VVRs can occur as an adverse event during interventional procedures for spine pain, with incidence rates ranging between 1.1% and 8% [6–8]. A study of more than 8,000 patients found that male sex, age (18–35), and pre-procedural pain score (<5/10) were associated with increased risk of VVR [6]. Another study reported greater likelihood of a VVR associated with cervical compared to lumbar spine injections (8% vs. 1%, respectively) [7]. A patient with a history of VVR during an interventional spine procedure is more than 7-times more likely (23% vs 3%) to experience a VVR during a subsequent procedure [9].

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Preprocedural considerations

Monitoring

Patient monitoring (pulse oximetry, non-invasive blood pressure monitoring, pulse) pre-, intra-, and post-procedure can help identify early bradycardia or hypotension. If a patient experiences a VVR during an interventional pain procedure, this information can assist the physician in determining the extent, duration, and management of the response. It is critical to differentiate VVR from other conditions such as cardiac syncope, allergic reaction, and high spinal block.

Moderate sedation in patients with documented history of VVR

A 2015 study reviewed 134 interventional procedures performed for patients with a history of previous VVR [9]. Of these, 90 procedures were performed without moderate sedation and 21/90 (23.3% [95% Confidence Interval (CI) 15.2-32.1%]) were complicated by a repeat VVR. Conversely, none of 44 repeat injections performed with moderate sedation resulted in a repeat VVR [0% (95% CI 0-9.6%)] ($\chi(2) = 12.17$, $P < 0.00048$). In fact, in this entire cohort, there were no VVRs in any patients, regardless of previous history, when moderate sedation was used. Therefore, in patients with a history of VVR, the use of moderate sedation may play a role in the prevention of repeat VVR.

Psychological distress

Psychological distress can trigger VVR [1,2]. Although the mechanism of the psychological trigger is unclear, strategies should be implemented to reduce anxiety, including informing patients about what they can expect during the procedure and designating a care team member to attend to the patient during the procedure.

Management considerations

Patient-performed physical counter-maneuvers

In both non-randomized and randomized trials, isometric muscle contractions have been shown to increase cardiac output and mean arterial blood pressure (MAP) while decreasing syncope occurrence [10,11]. The most effective maneuver combines leg crossing and buttocks clenching, but improvement in MAP can also occur with arm contractions. This effect seems to be mediated largely by the sympathetic nervous system increasing vascular resistance during the maneuvers, as well as mechanical compression of the venous vascular beds in the legs and abdomen. Unfortunately, such maneuvers may not be practical for use during the performance of an interventional pain procedure in which the patient is most often prone, and significant movement while a needle is in place is not advisable. However, these maneuvers could be useful once the needle is removed.

Trendelenburg position vs. passive leg raise

Trendelenburg position, in which the patient is placed at an angle with the feet above the head may be used to treat early symptoms of VVR. However, this maneuver does not appear to have a substantial effect on the vascular system; fifteen degrees of tilt in healthy normovolemic patients resulted in only 1.8% central displacement of blood volume [12]. Another study suggested that there was no clinically significant change in cardiac output, cardiac index, MAP, systemic vascular resistance, and oxygenation with 10-30° of Trendelenburg in critically ill patients [13].

In post-operative patients, Trendelenburg position has shown to increase MAP an average of 10.7 mm Hg ± 3.5 mm Hg, but this may not be associated with an improvement in blood flow or oxygenation [14]. Others postulate that the fluid shifts that occur with Trendelenburg positioning may ultimately result in decreased cardiac output [15,16].

In the case of hypovolemia, a meta-analysis of 21 studies reported that Trendelenburg position increases cardiac output by 9%, or 0.35 L/min, and passive leg raise increases cardiac output by 6%, or 0.19 L/min [17] at 1 min following the positional intervention. However, between 2 and 10 min post-positional intervention, only passive leg raise demonstrated sustained cardiac output benefits.

Ammonia inhalants

Ammonia inhalants have traditionally been used as a means for arousing a patient that has lost consciousness. There is no literature pertinent to the use of such agents in the context of a VVR due to a medical intervention. Given that ammonia inhalants are a noxious stimulus, caution is warranted, especially in patients with respiratory comorbidities [18].

Intravenous (IV) fluids

In cases where bradycardia leads to hypotension, if IV access is available, consideration can be given to administering a bolus of IV fluids as a means of increasing MAP [19].

Ice packs

In many instances, patients respond to cooling measures to counteract the parasympathetic state of VVR. Physiologically, a hypothermic state will trigger the sympathetic system to increase cardiac contractility and stroke volume to restore cardiac output. Ice has traditionally been considered as a means for triggering this phenomenon. Cold stimulation to the lateral neck has been shown to increase heart rate variability [20].

Summary and recommendations

- VVR can occur during interventional pain procedures. Differentiating this response from other conditions such as cardiac syncope, allergic reaction, or high spinal block is critical to its management.
- Younger age, male sex, and history of VVR are associated with an increased likelihood of VVR.
- Patient monitoring (pulse oximetry, non-invasive blood pressure monitoring, pulse) pre-, intra-, and post-procedure can help identify early bradycardia or hypotension.
- Many treatments historically used during VVR are supported by limited evidence. The magnitude of their effectiveness is unknown in the context of interventional pain procedures.
- The use of moderate sedation in select patients, particularly those with a history of VVR, demonstrates effectiveness in the prevention of VVR.

FACTFINDERS FOR PATIENT SAFETY

Spinal Cord Stimulator Trial Lead Migration

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Myth: The use of proper anchoring techniques will successfully mitigate safety concerns related to lead migration during spinal cord stimulation (SCS) trials.

Fact: Suturing percutaneous SCS leads does not mitigate the risk of migration compared to taping alone during a trial. Most lead migration does not pose a safety concern during the trial period.

Spinal cord stimulation (SCS), is FDA-approved for the treatment of failed back surgery syndrome, complex regional pain syndrome and painful neuropathy, among other conditions. Typically, a trial (temporary or permanent) is performed, and implantation is considered if the patient reports at least 50% relief of their index pain [21]. SCS lead migration has been reported to range from 13 to 22% [22,23]. Techniques to limit SCS lead migration, particularly during implantation, have improved over the years but this complication remains a primary reason for explant [24,25]. Data describing trial SCS lead migration is more scarce, with a rates as low as 0.7% [23] but up to 23% [26]. Investigators have sought to identify risk factors for SCS lead migration during trials in order to identify precautionary measures.

Risk factors for spinal cord stimulation lead migration

Understanding the risks for SCS lead migration provides insight in identifying those patients who may be most susceptible to the occurrence. Unfortunately, there is a paucity of evidence addressing such risk factors, particularly for SCS trials. Kumar et al. reported that lead migration, including both percutaneous and paddle leads, after implantation occurred more often in the cervical than thoracic spine [27]. It was suggested that this finding might be related to the greater degree of mobility in the cervical compared to thoracic spine. A different study evaluated reasons for readmission within 30 days of SCS lead implantation and identified lead migration and infection as the two most common causes [28]. Only one medical comorbidity (obesity) was an independent predictor of readmission (OR 1.86 [CI 1.18, 2.95]; p value 0.008), however, it was not associated with any specific readmission diagnosis (*i.e.* lead migration). These studies only provide circumstantial evidence that the level of lead placement and patient co-morbidities, specifically obesity, may be related to lead migration. There is no evidence available regarding the level of epidural entry and its effect on lead migration during SCS trials.

Spinal cord stimulation trial lead anchoring techniques

Osborne et al. investigated whether suturing through a silastic anchor and taping versus taping alone limited SCS lead migration during a three-day trial [29]. In both groups, the leads were taped in a "fan-like manner" and looped caudal to the entry point on the skin. The taping technique involved applying an adhesive to the skin and wrapping a strip of skin closure tape around the lead with subsequent affixation to the skin with additional tape applied sequentially along the lead. The mean distance of lead migration (caudal) was 24.49 mm (SD 11.3) in the suture and tape group compared to 8.72 mm (SD 5.77) in the tape only group ($p = 0.001$, 95% CI: 7.3-24.2). As a clinical reference, the average disc height of T8-9 has been reported to be 5.3 mm and with T8 vertebral body height of 18.5 mm [30]. The increased migration in the suture and tape group was felt to be due to increased tension on the lead resulting in an "inch worm" effect with flexion-based activities.

Efforts have also been made to investigate the ability of intrinsic anatomical structures as anchors that may be capable of limiting SCS lead migration. Mironer et al. retrospectively compared patients who underwent a "traditional trial" with ipsilateral (unilateral pain) or midline (bilateral pain) single-lead placement versus a group that underwent "midline anchoring" technique which theoretically engages the *plica mediana dorsalis* to stabilize the lead [26]. The *plica median dorsalis* is a band of connective tissue between the ligamentum flavum and dura. This was performed by introducing the lead from the contralateral side to the patient's symptoms. A significant difference in migration rate, 23% (11-48%) in the ipsilateral approach compared to 6% (2-15%) in the contralateral approach, was noted. Notably, there were no complications associated with the observed migrations. Unfortunately, lead migration itself was not confirmed by imaging to quantify the migration or assess the plane of migration (vertical or transverse) and based solely on symptom coverage. An acknowledged limitation in applying the contralateral technique is the variable morphology of the *plica mediana dorsalis* [31]. Transverse migration is not well studied in SCS trials. Long-term experiences with SCS implants reveals that the majority of migration occurs in a cephalocaudad (vertical) dimension [27].

Positional changes that influence migration

Many physicians advise patients to avoid bending, lifting or twisting during the SCS trial period in order to prevent lead migration. Kim et al. assessed SCS lead migration associated with positional changes at the end of a 7-day trial period in a total of 24 patients [32]. Leads were sutured and secured via wound closure strips to the skin. At the end of the seven-day trial period, patients with sufficient pain relief to proceed with implantation were divided into two groups representing those who experienced a change in paresthesia during the trial and those who did not. Imaging was performed with the patients in sitting and standing positions. There was an average caudal lead migration of 2.85 mm (95% CI: 2.3-3.4) in the group that noted paresthesia change during the trial. In patients who did not experience a change in paresthesias, there was a mean lead migration in the caudad direction of 3.24 mm (95% CI: 2.69 -3.79). These data suggest that there was no significant difference in lead migration when comparing those patients who experienced a change in paresthesia to those who did not.

Complications related to spinal cord stimulation lead migration

There is a case report of cephalad lead migration to the C2 level from a thoracic SCS lead placement [31]. The patient noted right upper extremity pain during a five-day trial after reporting that the original bandage had lost adherence and a new one was applied at home. The SCS leads were removed in clinic without complication and antibiotics were started to account for the possibility of skin flora introduction into the epidural space. Another case involved a patient being treated for failed back surgery syndrome with sutured trial leads placed at T8 and T9 who described chest pain and chest wall paresthesia on the second day of the trial [33]. A cardiac work-up was negative and the imaging revealed that one of the leads had migrated to the T1 level. The leads were eventually removed without further complication. These cases confirm that the leads can migrate great distances and cause new symptoms or result in loss of pain coverage.

Summary

1. Lead migration during SCS trial does not appear to result in long-term patient sequelae, but may cause new pain, impact treatment efficacy or require a repeat or revision procedure.
2. Lead suturing does not eliminate lead migration and there is evidence that it could paradoxically increase lead migration compared to taping alone. The effectiveness of specific anchoring techniques remains speculative.
3. It is reasonable to advise patients to follow post-procedure restrictions during the trial period including avoiding any bending or twisting, and to abstain from manipulation of the procedure site.
4. Counsel the patient on potential symptoms of lead migration including decreased pain relief, new pain, paresthesias in locations not observed initially, and any neurologic changes. This should prompt x-ray imaging to assess the location of trial leads.
5. Although cephalad lead migration has been observed, caudal migration is more common.
6. It is advisable to perform an x-ray to confirm the level of the electrodes at the end of the SCS trial in order to determine if lead migration occurred during the trial period if the decision to proceed with implantation is made.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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