Utilizing a Sedation Decision Aid in Ambulatory Venous Access Device Placement: Effects on Patient Choice, Workup, and Recovery Time

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Abstract
This study was undertaken to determine the influence of using a sedation decision aid when selecting a sedation option for totally implantable vascular access device placement on patient choice, workup, and recovery time. An institutional review board-approved, Health Insurance Portability and Accountability Act-compliant, retrospective study of 76 patients (aged 23-89 years, 58% female) presenting to a vascular interventional radiology department between January 2, 2017, and May 5, 2017. Patients were given a decision aid that inquired about personal values and goals, and provided information about expectations; benefits; and risks of the options, including undergoing the procedure with no sedation (local anesthetic), minimal sedation (anxiolysis with a benzodiazepine), or moderate sedation (benzodiazepine and opiate). No sedation was selected by 15 out of 76 patients (19.7%), minimal sedation was selected by 26 out of 76 patients (34.2%), and moderate sedation was selected by 34 out of 76 patients (44.7%). Postprocedure recovery time differences were significant (P < .001) with a mean of 17.4 minutes for no sedation, 49.3 minutes for minimal sedation, and 70.8 minutes for moderate sedation. The use of a decision aid did not slow down the process because workup times were not significantly different: 15.9 minutes for no sedation, 22.1 minutes for minimal sedation, and 18.4 minutes for moderate sedation. Patient sedation preference for totally implantable vascular access device is variable, signifying there is a role for utilizing a decision aid because it empowers a patient to select the option most aligned with his or her goals. Influence on departmental flow is notable because this does not slow down the workup and a majority of patients choose no or minimal sedation, resulting in a decreased postprocedure recovery time burden.

Background
Shared decision making is a collaborative process wherein providers present the treatment options available and empower a patient to be an active participant in selecting the therapy that is best aligned with his or her individual values and goals. Both the Affordable Care Act and the Institute of Medicine support shared decision making as a critical element of patient-centered care.1-4 Decision aids are tools that help patients become more involved in decision making by explaining the decisions that need to be made; providing information about the options, outcomes, risks, and benefits; and clarifying personal values and goals. They have proven highly effective in increasing decision quality, engaging patients, and addressing over- and underuse.5

Multiple publications have demonstrated a role for shared decision making in regard to selecting a sedation option before brief vascular procedures because patient sedation preferences

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are variable. To our knowledge, there is no published literature about the influence of employing a decision aid to facilitate this decision-making process. This study was undertaken to determine how using a sedation decision aid to present 3 sedation options influences patient choice, satisfaction, preprocedure workup, and recovery time. The 3 options were no sedation (local anesthetic only), minimal sedation (anxiolyis with a benzodiazepine), or moderate sedation (combination of an opioid for pain control and a benzodiazepine that serves as an anxiolytic while promoting amnesia).

Methods

Decision Aid Development

Three clinicians (MC, JL, and CS) attended a workshop offered by the Health Decision Sciences Center at our institution designed to help clinicians create, evaluate, and implement decision aids. The draft decision aid was a double-sided handout focused on decision about type of sedation. The first section of the decision aid explores patient goals through 5 questions that asks patients to rate importance of common features: not feeling “groggy” or “out of it,” being awake as long as I don’t feel pain, avoiding a long recovery time, being drowsy and waking up when the procedure is over, and being able to drive or work today. Patients were asked to rate each question on a scale of 1-3, where 1 represented “not important,” 2 represented “somewhat important,” and 3 represented “very important.” In the second section, the 3 sedation options were laid out in a table with key information about each option, including some reasons to choose it and reasons not to choose it (Figure 1).

The draft decision aid was reviewed by experts in decision sciences, physicians, and other workshop participants. The decision aid was also reviewed and edited by a health education project specialist at the Maxwell and Eleanor Blum Patient and Family Learning Center to ensure content was in plain language, layout was optimized for readability, the tone was welcoming, and that it used appropriate terms to improve health literacy. Lastly, the decision aid was presented to our institution’s Patient and Family Advisory Council during which experienced patients and family members were given an opportunity to provide feedback and input about the format, content, and process. After incorporating feedback from these reviews, the paper-based Sedation Decision Worksheet was finalized.

Decision Aid Implementation

Three vascular specialists (MC, JL, and CS) who participated in the development of the decision aid implemented the new tool with their patients. At the point of check-in for the procedure, patients were given the decision aid to review in the waiting area. The decision aid was reviewed by the vascular specialist and a shared decision-making discussion occurred following the 3-step model proposed by Elwyn et al. This discussion took place immediately before the procedure in a room off the preprocedure workup area. Family members were invited to be present for the discussion. Options were framed in the same way each time to achieve standardization. This included introducing the idea that there is choice in sedation and reasonable options available; describing in detail the options available, including risks, benefits, alternatives, medications used, possible side effects from sedation (eg, postoperative nausea, vomiting, impaired cognitive function, coordination, and respiratory and spontaneous ventilation); intraprocedure and recovery room expectations; and supporting patients in the decision-making process, including encouraging discussion with the family, supporting deliberation about the pros and cons of each option, helping patients explore their comfort levels through asking about their goals for the experience and empowering them to make a decision consistent with their preference.

Sedation Procedure Details

All patients received 18 cc 1% local lidocaine buffered with 2 cc 8.4% sodium bicarbonate to anesthetize the procedure site. The amount of medication used for minimal sedation was selected based on patient preference of an oral benzodiazepine (1 mg sublingual lorazepam administered 15 minutes before the procedure) vs an intravenous benzodiazepine (1-4 mg [intravenous [IV] midazolam] titrated intraprocedurally to minimal sedation. If IV sedation was preferred, the amount administered was determined using a standard sedation order set that specified the following dosing: midazolam 0.5 mg IV push every 3 minutes × 2 doses and then 0.5-1 mg IV push every 3 minutes × 8 doses per need (titrated to minimal or moderate sedation. Fentanyl 12.5 μg IV push every 3 minutes × 2 doses and 12.5-50 μg IV every 3 minutes × 6 doses per need given in combination with a benzodiazepine and titrated to moderate sedation. Nurses trained and certified in procedural sedation administered the IV medications as ordered and titrated the medication level to minimal or moderate sedation. With minimal sedation the aim was for the patient to be tired and sleepy but respond appropriately to verbal conversation and sounds. For moderate sedation, the aim was for the patient to be somnolent and sleeping but easily aroused with light tactile stimulation. Written informed procedural consent was obtained that included a section on consenting for procedure sedation, including the risks, benefits, side effects, and alternatives. All patients were offered on-demand sedation based on the discomfort of their experience. This meant they were instructed to request additional medications if they believed they needed them at any point.

Outcomes Measures

Procedures were performed by 1 of 3 licensed practitioners, each of whom had more than 5 years of experience placing totally implantable vascular access devices. Sedation option selection, completion under original sedation selection, sedation complications, adverse procedure events, intraprocedure time, time burden associated with preprocedure workup, postprocedure recovery onsite, and the responses to the 5 questions on the decision aid were tracked. Patients were discharged once their Aldrete procedural sedation recovery assessment score exceeded 10 points. The Aldrete scale is a validated tool used in our department as a measurement of recovery after sedation that includes gauging consciousness, activity, respiration, oxygen saturation, pain, and blood pressure. A point value from 0-2 is assigned for each category and summed to get a total score up
to 14. A score of 10-12 indicates the patient is ready for discharge. In addition, the following criteria were met: hemoglobin oxygen saturation > 93% or at presedation baseline; mental status returned to baseline, protective reflexes intact, state of hydration adequate, cardiovascular function and airway stable, and mobility at preprocedure baseline level. If patients were stable and had received only local anesthetic, they did not need to return to the recovery room and could be discharged home from the procedural suite after a nurse had reviewed all discharge instructions. An escort home was required if the patient received minimal or moderate sedation but not if the patient received no sedation (local anesthetic only). Preprocedure workup and

Figure 1. Sedation decision aid. This form was given to patients at the time of procedure check-in and completed in the preprocedure waiting area. It was reviewed by the procedure operator and discussed as part of a shared decision-making discussion with the patient and family before the procedure.
recovery room time was collected from the patient’s electronic medical flow chart where nurses record the time in and time out of the recovery room.

**Intervention Sample**

In this institutional review board-approved, Health Insurance Portability and Accountability Act-compliant, retrospective study, 77 patients who presented consecutively to a single-center ambulatory vascular interventional radiology department for placement of a totally implantable vascular access device seen by the 3 participating vascular specialists between February 1, 2017, and May 15, 2017, were included as the intervention cohort for the study.

**Historical Control Sample**

A historical sample was identified for comparison from the time before employing shared decision making and the sedation decision aid. A chart review was performed on a sample of 59 patients from the same vascular specialists, who presented consecutively for totally implantable vascular access device between April 3, 2013, and July 1, 2013. Both sedation type and the rationale for that sedation option were obtained from the procedure report. Preprocedure workup and recovery room time was obtained from the electronic medical record nursing flow sheets.

**Statistical Analyses**

We compared the sedation choices between the two groups using $\chi^2$ tests. Our hypothesis was that the intervention group would have fewer patients choosing moderate sedation. We compared the workup time and recovery time among the groups using analyses of variance. Post hoc analyses were used to compare differences in workup and recovery time 2 groups at a time. We also examined the factors associated with patients’ choices, including gender, age, and ratings of the importance of each goal.

### Table 1. Sedation Levels, Options, and Agents

<table>
<thead>
<tr>
<th>Levels of procedural sedation/patient options</th>
<th>Description</th>
<th>Agents used in our department</th>
</tr>
</thead>
<tbody>
<tr>
<td>No sedation (local anesthetic only)</td>
<td>Local anesthetic injected into the subcutaneous tissue at the procedural site. No effect on cognitive function, coordination, respiratory/ventilatory, cardiovascular, or neuromuscular function</td>
<td>1% Lidoacaine buffered with 8.4% sodium bicarbonate in a 10:1 ratio. Temporarily blocks the pathway of pain signals along nerves</td>
</tr>
<tr>
<td>Minimal sedation (anxiolysis)</td>
<td>Drug-induced state where patients respond normally to verbal commands. Cognitive function and coordination may be impaired. Respiratory and cardiovascular functions are normal</td>
<td>Benzodiazepines (intravenous midazolam or sublingual lorazepam). Agonists on the GABA-receptors. Effects include amnesia and anxiolysis</td>
</tr>
<tr>
<td>Moderate sedation (ie, conscious sedation)</td>
<td>Drug-induced depression of consciousness where patients respond purposefully to verbal commands alone or with light tactile stimulation. Cognitive function and coordination impaired. Respiratory, cardiovascular, spontaneous ventilation is adequate and no interventions are required to maintain a patent airway</td>
<td>Benzodiazepines (as above) and opioids (fentanyl). Act on opioid receptors: effects include analgesia, minimal anxiolysis and better control of sympathetic function.</td>
</tr>
<tr>
<td>Deep sedation (not offered as an option for TIVAD)</td>
<td>Drug induced depression of consciousness where patients cannot be easily aroused but respond after repeated or painful stimuli. Cognitive function and coordination impaired. Respiratory and spontaneous ventilation may be impaired and patient may require assistance in maintaining a patent airway. Cardiovascular function is usually maintained.</td>
<td>Same agents as moderate sedation above. Not performed by interventional radiologist at our institution</td>
</tr>
<tr>
<td>General anesthesia (not offered as an option for TIVAD)</td>
<td>Drug-induced loss of consciousness where patients are nonarousable by painful stimuli. Independent respiratory, ventilatory and neuromuscular function is often impaired and patient requires assistance to maintain a patent airway; positive pressure ventilation may be required. Cardiovascular function may be impaired.</td>
<td>Multiple agents, including opioids, benzodiazepines, and paralytics, under the discretion of anesthesiologists</td>
</tr>
</tbody>
</table>

IR = Interventional Radiology; GABA = Gamma-aminobutyric Acid; TIVAD = Totally Implantable Vascular Access Device.
in the first section of the decision aid. The statistical software package SPSS version 20 (SPSS Inc, Cary, NC) was used for all analyses with a $P$ value $< .05$ considered to be statistically significant.

**Results**

The intervention sample was on average 59 ± 15.6 years old and 58% female. The sample had more than 30 different diagnoses, the most common were breast cancer (16%) and pancreatic cancer (12%). The historical control sample was on average 61 ± 14 years old and 64% female, and had a similar variety of diagnoses.

No sedation (local anesthetic only) was selected by 15 out of 76 patients (19.7%), minimal sedation was chosen by 26 out of 76 patients (34.2%), and moderate sedation was chosen by 34 out of 76 patients (44.7%). All patients completed the procedure with the option they initially selected without requiring a higher level of sedation. Medication amounts for minimal sedation ranged from 1 mg sublingual lorazepam to 4 mg IV midazolam. Medication amounts for moderate sedation ranged from 1.5 mg IV midazolam with 75 µg IV fentanyl to 4 mg IV midazolam with 200 µg IV fentanyl. The historical comparison revealed 4 out of 59 patients (6.8%) underwent the procedure with no sedation, 6 out of 59 patients (10.2%) underwent the procedure with minimal sedation, and 49 out of 59 patients (83%) underwent the procedure with moderate sedation. The sedation choices were significantly different in the intervention and control groups ($F[2, 72] = 25.2; P < .001$). Post hoc comparisons using the Tukey honest significant difference test found significantly longer recovery time for the mild sedation vs no sedation group ($P < .001$); for moderate sedation vs mild sedation group ($P = .003$); and for moderate sedation vs no sedation group ($P < .001$).

Sedation choice was not associated with gender ($P = .49$) or age ($P = .24$). Patient ratings of goals did vary by sedation choice (see Figure 2). Four of the 5 goals not wanting to feel groggy ($P = .05$), wanting to stay awake ($P < .001$), not wanting a long recovery ($P < .001$), and wanting to return to work ($P = .01$) all discriminated significantly among the options. The relationships were in the appropriate direction (with “mild sedation” always between the “no sedation” and “moderate sedation” options).

**Discussion**

Sedation patterns for ambulatory vascular procedures are highly variable with differing amounts and levels of sedation as well as unique adjunctive methods being used for similar procedures in different institutions. Sedation choice is often determined by the habits and philosophies of the institution and based on assumption that patients will be more satisfied with deeper sedation, which multiple studies have shown is misguided. There is therefore a need for a more patient-oriented approach to sedation that is individualized; involves a discussion about the various options; and takes into consideration patient preferences, anxiety, pain tolerance, anticipated pain, and length of procedure. Decision aids are tools that can help patients select the sedation option consistent with their values.

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**Figure 2.** Patient goals for sedation and sedation selection, illustrating how patients’ ratings of the importance of each goal varied by their sedation choice.
Before our implementing a sedation decision aid, 49 out of 59 patients (83%) underwent their procedure with the moderate sedation option that is associated with more risk, time, and monitoring requirements compared with mild or no sedation options. After implementing the decision aid, the rate of moderate sedation was cut in half, with only 44% of patients choosing moderate sedation. The workup time did not vary across procedures, but the recovery time was significantly higher for moderate sedation. As a result, reducing use of moderate sedation has had a significant, positive influence on department flow. Nurses noted that when patients underwent the procedure with local anesthetic it improved the overall efficiency (less need for nurse monitoring, a more rapid turnaround, and a shorter recovery time) and they found discharge planning easier as amnesic effects were lessened. Further evaluation looking at the amount of medications used and the cost associated with the different sedation scenarios could help understand the influence a sedation decision aid might have on health care costs.

The elements of shared decision making are more likely to be followed if a decision aid or tool is used during a clinician visit and as part of the decision-making conversation. Utilizing a decision aid did not add significant time burden to preprocedure workup time or to the operators’ workload and thus has become the standard of care for our department. It is important to note that face-to-face shared decision-making discussions continue to occur with patients and families because decision aids are meant to complement, rather than replace counseling from a health practitioner.

**Limitations**
This project was a retrospective study and neither specialists nor patients were randomized nor blinded to the intervention. The 3 participating specialists took a course on shared decision making and created the decision aid. It is possible the influence would be different with specialists not involved in the development. Operator skill plays a substantial role in being able to perform these procedures without sedation, and the operators in this study are vascular physician assistants and nurse practitioners who are highly specialized in venous access device placement; thus, results may not be generalizable to other providers. These data refer only to using a sedation decision aid before vascular device placement. Additional data would be needed to consider shared decision making for other vascular procedures. Finally, this study was performed in a tertiary care academic medical center; a limitation might be difficulty in generalizing to other ambulatory vascular practice patterns.

**Conclusions**
Utilizing a sedation decision aid for totally implantable vascular access device placement enables patients to select a sedation option most consistent with their values and preferences, leading to a reduction in using the higher levels of sedation. The influence on departmental flow is notable because there is no significant increase in preprocedure workup time and patients frequently choose a lower level of sedation (no or minimal sedation), resulting in a decreased postprocedure recovery time burden.

**Disclosure**
The authors have no conflicts of interest to disclose.

**Acknowledgment**
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**References**


