Published in final edited form as:

J Vasc Interv Radiol. 2017 December ; 28(12): 1732–1738. doi:10.1016/j.jvir.2017.07.014.

Effects of Patients' Affect on Adverse Procedural Events during Image-Guided Interventions

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Abstract

Purpose—To assess how a patients' affect on presentation relates to the likelihood of adverse events during their subsequent interventional image-guided procedures.

Materials and Methods—A secondary analysis was performed of an existing data set from a clinical trial with 230 patients who underwent percutaneous peripheral vascular and renal interventions and who had completed the Positive Affect Negative Affect Schedule (PANAS) prior to their procedures. Summary PANAS scores were split over the median and used to classify the participants into those with high versus low positive and high versus low negative affect. Associations between affect and the absence or presence of adverse medical events were examined using two-sided Fisher exact tests.

Results—Patients with high baseline negative affect were significantly more likely to have adverse events during their procedures than those with low baseline negative affect (18% vs 8%, $p=0.030$). High baseline positive affect was not associated with a significantly higher frequency of subsequent adverse events compared to low positive affect (15% vs 9%, $p=0.23$). Patients with high negative affect requested and received significantly more sedatives and opioids than those with low negative affect (2.0 vs 1.0 units requested, $p=0.0009$; 3.0 vs 1.0 units received, $p=0.0004$). Positive affect levels did not affect medication use.

Conclusion—High negative affect, but not positive affect, was associated with an increased likelihood of adverse events. Improving patients' negative affect prior to procedures seems a more suitable target towards improving the procedural experience than attempting to boost their positive affect.

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INTRODUCTION

Distress in the radiology waiting room runs high, and many patients display negative emotions on arrival (1). Expectancies have been shown to elicit outcomes in terms of self-fulfilling prophecies in social and some medical contexts (2, 3). It is unclear, however, the extent to which a patients' negative thoughts/beliefs might affect interventional procedural complications, although it is known that patients who express their negative feelings in speech and behavior can have adverse effects on medical team performance (4). In addition, very little is known regarding the associations between a patient's *positive* attitudes and the outcomes of medical procedures.

Patients' mood in the medical context is commonly assessed by the degree of negative affect and positive affect a person endorses (5, 6). Negative affect (NA) refers to moods of individuals who feel distressed, guilty, fearful, angry, and nervous, are not satisfied, and come across as hostile (7). High negative affect can decrease pain tolerance (8) and has been associated with increased systolic blood pressure (9), cardiovascular disease (10–12), impaired immune function (13), irritable bowel syndrome (14), poor physical responses to stress (15), and dysregulation of the autonomic nervous system (16).

High levels of positive affect (PA) reflect a pleasurable engagement with the environment and are associated with enthusiasm, energy, and attention. Positive affect is not the opposite of negative affect; both can coexist (5). For example, one can be upset about something and express that opinion with great outward energy (e.g., politics), or one can also be very excited about and yet anxious of an upcoming event (e.g., wedding). Research suggests that positive emotions support cardiovascular health and resilience, particularly in healthy populations, although the effects of PA in disease states and during acute stress management are less clear (17–19).

Given these considerations, this study tested the hypothesis that high NA of a patient upon presentation is associated with a greater likelihood of adverse physiologic events during interventions and that PA is associated with improved procedural tolerance. These hypotheses were tested using a validated tool for the assessment of positive and negative affect (PANAS) in patients and correlating NA and PA with adverse events recorded during vascular and renal procedures.

METHODS

Patients

This study was IRB-approved and Health Insurance Portability and Accountability Act (HIPAA) compliant. This current study is the secondary analysis of previously unpublished data collected during an interventional trial (20). The purpose of the original study was to compare two methods of non-pharmacologic analgesia for invasive procedures, while this new analysis investigates hypothesized relationships between baseline patient affect and the occurrence of adverse events.

Eligible individuals for the original study were adults referred for percutaneous trans-catheter diagnostic and therapeutic peripheral vascular and renal interventions at a tertiary medical center. Exclusion criteria were severe chronic obstructive pulmonary disease, psychosis, intolerance of midazolam or fentanyl, pregnancy, inability to hear or understand English. Patients were asked to participate in a research study to assess whether a relaxation exercise would enhance comfort during an invasive procedure. They were told that their chance to be guided in the exercise was one in three. In the original study, 241 of 366 eligible patients were enrolled and randomized to standard care, empathic attention, or guidance in self-hypnotic relaxation consisting of a combination of empathic attention plus being read a script. After consent and prior to revelation of randomization, patients were given a Positive and Negative Affect Schedule (PANAS) (5, 6) to fill out. Of the 241 patients, 230 returned the completed PANAS and represent the study population for the current study.

The intake forms of the original study documented the procedure category for each patient. The category “Arterial” was mainly used for assessment of peripheral vascular disease or aortic aneurysms and commonly included run-off studies of the lower extremities without or with intervention. “Arterial” was also used for assessment and treatment planning of hepatic and renal tumors. The “Arterial and venous” category was used for vascular mapping in the context of hepatic or renal organ transplantation (donors or recipients). “Venous” was used for venous occlusions, commonly in conjunction with venous access assessment or flow restoration for dialysis fistulae. “Percutaneous renal” was used for nephrostomies or nephro-ureteral stent placement.

Classification of baseline morbidity was based on the American Society of Anesthesiologists (ASA) classification and was entered in the clinical pre-procedure sedation work-up sheets with the following definitions: ASA I for a healthy person, ASA II for mild systemic disease, ASA III for severe systemic disease, and ASA IV for systemic disease that is a constant threat to life. In addition, a disease category classification was devised as follows: 1=benign, no threat to limb or life; 2=benign, threat to limb or organ, no threat to life; 3=malignant; 4=acutely life-threatening.

Affect Assessments

The PANAS contains a list of 20 adjectives, each related to either positive affect (PA) or negative affect (NA) (Figure 1). The 10 PANAS NA adjectives are distressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery, and afraid. The 10 PANAS PA adjectives are interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive, and active. Respondents were asked to “...indicate to what extent you feel this way in general, on average” for each adjective on a 5-point Likert scale, ranging from “1 = Very slightly/Not at all” to “5 = Extremely.” Scores were summed to create separate PA and NA scores, which may range from 10 to 50. Higher scores indicate higher levels of NA or PA affect.

Adverse Procedural Events

An adverse event was defined as one or more of the following physiological events: prolonged hypoxia <89%, de novo hypertensive or hypotensive episodes, prolonged de novo

bradycardia, cardiac arrhythmia, procedure interruption for restoration of hemodynamic stability, severe nausea, or over-sedation with somnolence, disorientation, or need for hospital admission. For the purposes of this study, physiological changes that did not divert the attention of the interventional radiologist, such as transient drops in oxygen saturation that were relieved by nasal prongs or a low heart rate that persisted from pre-procedural baseline in an otherwise hemodynamically stable patient, were not counted as adverse events.

Medication Use

IV sedation was provided in a patient-controlled analgesia model where patients received, upon pushing a button, nurse-administered midazolam and fentanyl in dosages of 1 unit (0.5 mg+25µg) x 4 with lockout times of 5 min, then with lock-out times of 15 min. Medication was withheld during lock-out times and when systolic blood pressure was below 89 mm Hg, oxygen saturation fell below 89%, or the patient developed slurred speech or became difficult to arouse. In rare cases, fentanyl and midazolam were administered without the patient's request for reasons of safety, such as when systolic blood pressure exceeded 180 mm Hg or if the patient expressed distress verbally.

Statistical Analysis

The median for total NA and PA was used to classify groups into high and low NA and PA categories. Using this method, all patients with an NA of ≥ 24 were classified as high NA, and all patients with NA <24 were classified as low NA. Similarly, patients with a PA of ≥ 27 were classified as high PA, and patients with PA <27 were classified as low PA. The presence or absence of adverse events was compared between the affect groups, and percentages were calculated. Presence of adverse events was coded on a per-patient basis regardless of how many adverse events the patient displayed.

Statistical significance of an association between categorical variables (such as presence of adverse events, affect group, and other categorical cohort variables) was tested using the Fisher exact test. Mean age was compared between groups with low and high affect or between groups with and without adverse events by the Student t test. Drug usage (total units administered or requested), which was not normally distributed, was compared between groups using the Mann-Whitney U test. Values of $p < 0.05$ were considered significant in two-tailed tests.

RESULTS

Distribution of Mood States

NA scores ranged from 14 to 35, with a median of 24 (mean 23.9, SD 4.3). PA scores ranged from 15 to 38, with a median of 27 (mean 27.7, SD 4.1). Of the patients with a high NA ($n=116$), 80% had a coexisting high PA ($n=93$). Of the patients with a low NA ($n=114$), 55% had a coexisting low PA ($n=63$) (Table 1).

Patient Characteristics

Among the 230 patients who completed the PANAS, there were 110 men and 120 women; the mean age was 54.6 years (SD 16.3 years, range: 18–92 years). Most of the patients were married (n=133), followed by single (n=44), widowed (n=29), divorced (n=21) and unknown (n=3). The majority of patients were Caucasian (n=220), and the remainder were African-American (n=9) or Native American (n=1). Patient characteristics of those who had low and high NA were similar in terms of number of patients, age, race, treatment group, procedure type, and disease category (Table 2). With regards to gender, there was a nonsignificant trend for more females in the high NA cohort and more males in the low NA cohort ($p=0.06$). With regards to the ASA classification, there was a nonsignificant trend towards an association between ASA score and NA group ($p=0.06$), with a tendency toward higher ASA scores (III–IV) in the cohort with low NA.

Procedural Adverse Events

There were 30 patients who had at least one adverse event (Table 3). A higher fraction of patients with high NA (21 of 116; 18%) experienced those than patients with low NA (9 of 114, 8%; $p=0.030$). High baseline positive affect was not associated with a significantly higher frequency of subsequent adverse events, relative to low positive affect (15% vs 9%, $p=0.228$). The distribution of high versus low NA and PA in patients with adverse events is shown in Figure 2. Twenty-two patients experienced one adverse event (16 in the high NA group and 6 in the low NA group); seven had two events (5 in the high NA group and 2 in the low NA group), and one patient in the low NA group became hypotensive and bradycardic and required transfer to the OR for bleeding control. The 39 events are listed in Table 3.

Among patients experiencing adverse events, 17 derived from the original standard care group (4 low NA, 13 high NA), 10 from the empathy group (5 low NA, 5 high NA), and 3 from the self-hypnotic relaxation group (all high NA). The association between treatment group and adverse events was statistically significant and was reported in the original study (20).

There was a significant association between adverse events and type of procedure performed ($p=0.001$). Overall, arterial/venous procedures had lower adverse events than venous and renal procedures.

Medication Use

Patients in the high NA group requested significantly more medication units (range 0–8, median 2.0) ($p=0.002$) and received significantly more medication units (range 0–9, median 2.0) ($p=0.001$) than those in the low NA group (requested: range 0–22, median 1.0; received: range 0–18, median 1.0). However, there was no significant difference in the amount of medications received between patients with high versus low PA (1.0 vs 1.0 medication units, $p=0.14$) or in the amount of medications requested between patients with high versus low PA (1.0 vs 1.0 medication units, $p=0.11$). There was a significantly higher number of medication units requested (range 0–12, median 2.0) ($p=0.0009$) and given (range 0–13, median 3.0)

($p=0.0004$) in patients with adverse events (Table 4) than those who did not have adverse events (requested: range 0–22, median 1.0; received: range 0–18, median 1.0).

DISCUSSION

In this study patients who presented with high NA were 2.3 times more likely to experience adverse cardiovascular and respiratory events during their image-guided interventions than patients with low NA. The underlying disease status or ASA classification of patients with NA was not significantly different from that of patients with low NA, and thus one would not have predicted a higher procedural risk based on physical morbidity. The group with more adverse events requested and received more medications during their cases. This may be in part due to the fact that high NA patients as a group requested and received more sedatives and narcotics and represent a higher fraction of patients with more adverse events. Although the higher medication dose might have accounted for the higher frequency of hypoxic events, the dosages administered were too low to fully explain the group differences. The median medication dosages of 3 units received by the patients with more adverse events correspond to 1.5 mg midazolam and 75 μ gm fentanyl which is far below what many authors cite as their standard average dosing regimen for vascular interventions (21). Notably, patients with more adverse events received more medications than they requested (median 3 vs 2 drug units), which was not the case for patients without adverse events or patients with high NA as a group. One might thus speculate that in the setting of increasing procedural risk, the interaction dynamics between patients and staff in the study may have changed with regard to perceived sedation needs.

NA as a psychosocial predictor of stress responses of the cardiovascular system has been evaluated with experiments designed to induce acute mental stress, such public speaking, math tests, or challenging interpersonal scenarios (15). In these settings high NA was associated with increased heart rate and blood pressure, as well as decreased cardiovascular reactivity and stress recovery. The author postulated that the body's natural ability to maintain an equilibrium in response to physiologic or environmental challenges depends on a harmonious interaction along the hypothalamic-pituitary-adrenocortical axis and autonomic nervous system, and that this mechanism, which enhances chances of survival, becomes disturbed in stressful settings (15). In support of this concept, high NA has been linked to hypercortisolemia, elevated plasma and urine catecholamines, impairment of platelet functions, elevated heart rate, reduced heart rate variability, and impaired vagal control (12, 16). Consistent with these findings, anger and hostility, subcomponents of the NA as measured by the PANAS, have been associated with a higher risk of future coronary heart disease in healthy populations and a poorer prognosis in those with existing coronary artery disease (22). There is some overlap between the adjectives defining NA ("jittery," "scared," "nervous", "afraid") and descriptors of anxiety. Pre-procedure anxiety, as measured by the Spielberger State-Trait-Anxiety inventory, has been shown to be a predictor of increased medication use to treat intraoperative pain during interventional radiological procedures (23).

Baseline PA was not significantly associated with the likelihood of procedural adverse events. Research on PA often focuses on the effects on healthy populations. A meta-analysis

of prospective studies relating psychosocial well-being to mortality showed mixed results: PA was associated with reduced mortality, but mostly in healthy populations, less so in populations with preexisting conditions (24). There is also concern about the possibility of publication bias in this area; that is, the possibility that studies finding positive associations may be more likely to be published than those finding no associations (24). The fact that greater PA did not improve hemodynamics may support the hypothesis that NA is the critical factor disturbing the heart rate variability profile as determinant of adverse cardiovascular events. In that context, if a heart rate variability profile is already sufficiently well-tuned, it might not become further improved by high PA, provided that NA is low.

The PANAS was developed to provide measures of PA and NA as distinct from one another (5) although complete independence between PA and NA has been questioned (6). Based on the measure's developers, the PANAS NA dimension may be understood to promote vigilant apprehension while the PA dimension reflects motivating goal-directed behaviors (25). A person who is very scared, distressed, or angry (high NA) may suffer quietly (low PA) or may communicate these feelings energetically (high PA). When patients express negativity overtly by being rude, such behavior has been shown to interfere with the ability of medical teams to function properly (4). It is difficult to gauge whether mood contagion of the treating team may have contributed to the higher incidence of adverse events in the high NA group (26).

Based on the current findings, patient mood matters. While few of the adverse events described can be considered complications, they can cause distraction of the operator and staff and could be indicative of worse outcomes to come. At a minimum, these adverse events likely increase the stress levels of the personnel. As such, interventions that help patients reduce high levels of NA could potentially also improve the working climate and resilience in addition to improving safety.

A number of studies have found that interventions that influence the stress response, such as those associated with interventional radiological procedures, are associated with less pain, less anxiety, fewer cardiovascular adverse events, reduced cardiac sympathetic hyperactivity, and improved heart rate variability profiles (20, 27–30). This is consistent with the finding that patients in the self-hypnotic relaxation group of the primary trial from which the data for these analyses were taken, including those with negative affect, had fewer adverse events (20).

The study has limitations that should be considered when interpreting the results. First, study subjects were asked to rate PA and NA from the perspective of their general mood, and not on the basis of their mood on that day. Research indicates that NA and PA may fluctuate, so different findings might have emerged had participants been asked to use the PANAS to rate their current mood. It appears, however, that NA is more stable from day to day than PA (25). It is possible that this stability might have contributed to the stronger association of NA with adverse events. Future researchers might consider asking participants to rate both their mood “in general” and their current mood to identify if this influences the associations with subsequent adverse events. Given the small cohort size (30 patients) and the differences in medication use and inter-individual differences in procedural detail, complexity, and

patients' baseline characteristics, it is difficult to clearly identify the mechanisms that play the most roles important in influencing the association between adverse events and negative affect. The association between increased medication use and patients with high NA is intriguing, but its possible causative role remains a subject for future studies.

Despite the study's limitations, the findings provide important new information regarding the association between mood and subsequent adverse events in individuals who undergo interventional procedures; specifically, patients endorsing high negative affect fared worse in terms of adverse events compared to patients who had low negative affect. Future research is required to determine if interventions that decrease NA lead to a reduction of adverse events in patients with high negative emotions undergoing radiology procedures.

Acknowledgments

This work was supported by the National Institutes of Health, National Center for Complementary and Integrative Medicine (RO1-AT-0002- and R44AT006296). The funding agency was not involved in the design and conduct of the study, data analysis, and approval of the manuscript. The content is solely the responsibility of the authors and does not necessarily reflect the official views of the funding agency.

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Below you will find a list of 20 words that describe different feelings and emotions. Please read each item and then mark the answer next to each item. Indicate to what extent you feel generally this way, that is, how you feel on average. Use this scale for your answers:
1= very slightly or not at all, 2= a little, 3= moderately, 4= quite a bit, 5=extremely

1	Interested		11	Irritable	
2	Distressed		12	Alert	
3	Excited		13	Ashamed	
4	Upset		14	Inspired	
5	Strong		15	Nervous	
6	Guilty		16	Determined	
7	Scared		17	Attentive	
8	Hostile		18	Jittery	
9	Enthusiastic		19	Active	
10	Proud		20	Afraid	

Figure 1. Positive Affect Negative Affect Schedule (PANAS), modified from Watson and Clark (5), as it was used in this study

To calculate the Positive Affect (PA) Score: Add the scores for items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. Scores can range from 10 – 50, with higher scores representing higher levels of PA. Similarly, to calculate the Negative Affect (NA) Score: Add the scores on items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. Scores can range from 10 – 50, with lower scores representing lower levels of NA.

Figure 2. Distribution of high and low positive affect (PA) and negative affect (NA) among 30 patients with adverse events

Note that the majority of patients with adverse events had a high NA (n=21) and most of them had a concomitant high PA (n=17)

Table 1
Distribution of scores for negative affect (NA) and positive affect (PA)

Scores were split over their respective medians into high and low NA and PA.

Affect	High NA	Low NA	Total
High PA	93	51	144
Low PA	23	63	86
Total	116	114	230

PA= Positive affect

NA= Negative affect

Table 2

Patient cohorts with high and low negative affect (NA). Percentages refer to percent of total patients within the high NA group or low NA group. P-values are computed from two-tailed t-tests (for age) or from two-tailed Fisher exact tests (for the categorical variables).

	High NA	Low NA	p-value
Number of patients	116	114	
Mean age (years)	52.9	56.4	0.10
Gender			0.06
Female	68 (59%)	52 (46%)	
Male	48 (41%)	62 (54%)	
Race			0.33
White	109 (94%)	111 (97%)	
Non-white or unknown	7 (6%)	3 (3%)	
Treatment group			0.28
Standard of care	44 (38%)	33 (29%)	
Empathic attention	33 (28%)	42 (37%)	
Self-hypnotic relaxation	39 (34%)	39 (34%)	
Procedure type			0.17
Arterial	63 (54%)	71 (62%)	
Venous	23 (20%)	27 (24%)	
Arterial and venous	10 (9%)	5 (4%)	
Percutaneous renal	20 (17%)	11 (10%)	
ASA classification			0.06
I	12 (10%)	7 (6%)	
II	69 (59%)	56 (49%)	
III	27 (23%)	43 (38%)	
IV	2 (2%)	5 (4%)	
Disease category			0.69
1	39 (34%)	40 (35%)	
2	62 (53%)	54 (47%)	
3	12 (10%)	17 (15%)	
4	3 (3%)	3 (3%)	

Table 3
Adverse events in patients with low and high negative affect (NA)

Note that several patients had more than one adverse event.

	Low NA	High NA
Bleeding	1	1
Hypertensive episodes	1	6
Hypotensive episodes	2	2
Bradycardic episodes	4	5
Tachycardia	1	
Premature ventricular contractions		1
Hypoxia	3	7
Oversedation	1	3
Severe nausea		1

Table 4

Relationship of cohort characteristics and occurrence of adverse events. Percentages in parentheses within the first 2 numeric columns refer to the percent of the total for the respective column. Percentages within the third numeric column represent rates of adverse events among patients included within a given row. P-values are computed from two-tailed t-tests (for age), from two-tailed Mann-Whitney U tests (for medication dosage), or from two-tailed Fisher exact tests (for the categorical variables).

	Adverse events	No adverse events	% with adverse events	p-value
Number of patients	30	200	13%	
Mean age (years)	56.0	54.4		0.62
Gender				0.70
Female	17 (57%)	103 (52%)	14%	
Male	13 (43%)	97 (49%)	12%	
Race				0.13
White	27 (90%)	193 (97%)	12%	
Non-white or unknown	3 (10%)	7 (4%)	30%	
Treatment group				0.003
Standard of care	17 (57%)	60 (30%)	22%	
Empathic attention	10 (33%)	65 (33%)	13%	
Self-hypnotic relaxation	3 (10%)	75 (38%)	4%	
Procedure type				0.001
Arterial	9 (30%)	125 (63%)	7%	
Venous	11 (37%)	39 (20%)	22%	
Arterial and venous	1 (3%)	14 (7%)	7%	
Percutaneous renal	9 (30%)	22 (11%)	29%	
ASA classification				0.09
I	0 (0%)	19 (10%)	0%	
II	21 (70%)	104 (52%)	17%	
III	6 (20%)	64 (32%)	9%	
IV	0 (0%)	7 (4%)	0%	
Disease category				0.42
1	7 (23%)	72 (36%)	9%	
2	19 (63%)	97 (49%)	16%	
3	4 (13%)	25 (13%)	14%	
4	0 (0%)	6 (3%)	0%	
Median medication units requested	2.0	1.0		0.0009
Median medication units given	3.0	1.0		0.0004

Note: Presence of adverse events was significantly associated with treatment group, procedure type, and amount of medications requested and given. ASA: American Society of Anesthesiologists