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Examining the Effect of an Animal-Assisted Intervention on Patient Distress in Outpatient Cystoscopy

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Animal assisted interventions (AAI) have been shown to improve patient outcomes in some healthcare settings. Flexible cystoscopy, while minimally invasive, is associated with patient-reported pain, fear, and anxiety. Few techniques have been found to improve these adverse effects associated with cystoscopy. The purpose of this study was to extend existing research on AAI in outpatient settings to investigate the effectiveness of AAI in reducing patient distress associated with outpatient cystoscopy. Ninety-five patients (average age 55.5 years) were prospectively enrolled and randomized to receive one 15-minute AAI prior to cystoscopy (n=46), or cystoscopy performed per standard protocol (n=49). Distress was measured by Visual Analogue Scales (VAS) for fear, anxiety, and stress, systolic blood pressure, and heart rate at 3 time points: prior to intervention/prior to cystoscopy, following intervention/prior to cystoscopy, and following intervention/following cystoscopy. Pain was assessed by VAS post-cystoscopy. There were no significant differences between the AAI and control groups in changes in systolic blood pressure, heart rate, fear, and pain between any time points. There were significant between-group differences in changes in anxiety and stress prior to cystoscopy with greater reductions found in anxiety and stress following AAI. The greater reductions in stress associated with AAI were maintained after cystoscopy. This is the first study to investigate the effectiveness of AAI in reducing distress associated with cystoscopy. More research is needed to determine if AAI is a viable method for improving patient outcomes associated with this and other outpatient procedures.

keywords: Animal-assisted interventions, cystoscopy, therapy dogs

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Flexible cystoscopy is an outpatient procedure commonly performed by urologists for both diagnostic and therapeutic indications. While minimally invasive, this procedure is associated with patient reported pain, fear, and anxiety (Cano-Garcia, Casares-Perez, Arrabal-Martin, Merino-Salas, & Arrabal-Polo, 2015; Cornel, Oosterwijk, & Kiemeney, 2008; Losco, Antoniou, & Mark, 2011; Mirheydar et al., 2015; Raheem, Mirheydar, Lee, Godebu, & Sakamoto, 2015). While it is estimated that 6.6 million cystoscopies are performed annually with 2.3 million occurring in the U.S. alone (Thompson, 2013), few effective interventions have emerged that consistently improve the patient experience. Higher irrigation pressure has been shown to improve patient comfort (Zhang et al., 2015), as has handholding during flexible cystoscopy which was reported to significantly reduce anxiety, pain, discomfort, and dissatisfaction (Kwon et al., 2018). Although two studies have demonstrated that listening to music during cystoscopy significantly reduced post-procedure anxiety and pain scores (Raheem et al., 2015; Zhang et al, 2014), a third study failed to replicate these findings (Mirheydar et al.,2015). Conflicting evidence also exists as to whether allowing patients to observe their own cystoscopy increases comfort (Cornel et al., 2008; Zhang, Tang, Wang, Xu, & Sun, 2011). Multiple other interventions have failed to demonstrate a reduction in cystoscopy-associated pain or anxiety, including the use of 2% topical lidocaine (Cano-Garcia et al., 2015; Patel, Jones, & Babineau, 2008), insertion of a combined local anesthetic lubricant into the urethra for 3 minutes prior to cystoscopy (Losco et al., 2011), or use of virtual reality distraction (Walker et al., 2014).

Interest in animal-assisted interventions (AAI) in health care settings is rising given increasing evidence of its therapeutic potential in targeting anxiety, stress, and other health-related outcomes associated with procedures and various disease states (Morrison, 2007; Snipelisky & Burton, 2014). AAI includes animal-assisted therapy (the purposeful incorporation of a therapy animal into a treatment plan to facilitate patient healing and recovery) and animal-assisted activities (involving therapy animals in a recreational or educational manner without specific treatment goals) (Griffin, McCune, Maholmes, & Hurley, 2011). In the health care setting, AAI typically involves a registered therapy dog and its owner visiting patients individually or in groups to provide comfort and distraction (S. Barker, Vokes, & Barker, 2019).

AAI efficacy research conducted in health care facilities has produced mixed results. Some evidence supports benefits of AAI associated with reduced anxiety (Barker & Dawson, 1998) and fear (Barker, Pandurangi, & Best, 2003) in hospitalized psychiatry patients, less depression among nursing home patients (Colombo, Buono, Smania, Raviola, & De Leo, 2006), reduced pain perception in pediatric patients (Sobo, Eng, & Kassity-Krich, 2006), improved cardiovascular function in congestive heart failure patients (Cole, Gawlinski, Steers, & Kotlerman, 2007), reduced pain and increased patient satisfaction following joint replacement surgery (Harper et al., 2015), and reduced pain medication use following joint replacement (Havey, Vlasses, Vlasses, Ludwig-Beymer, & Hackbarth, 2014). Benefits have also extended to health care professionals whose salivary and serum cortisol levels significantly declined after as little as five minutes of AAI (Barker, Knisely, McCain, & Best, 2005).

Few studies have examined the effect of AAI in the outpatient setting or during outpatient procedures. In general, studies that have been published suffer from a lack of methodological rigor, making it difficult to draw conclusions. Investigating the efficacy of AAI in a pediatric oncology outpatient clinic, investigators found a significant reduction in pain, irritation, and stress following three 30-minute AAI group sessions in a convenience sample of children with leukemia and solid tumors, but no significant effect on mood, anxiety, depression, quality of life, heart rate, or blood pressure (Silva & Osorio, 2018). Two studies investigated the effect of AAI on convenience samples of patients receiving outpatient pain management treatment. In the first study, chronic pain management patients choosing a waiting room with a therapy dog were compared with patients in a waiting room without a dog. Patients in the AAI group reported improved pain, mood, and emotional distress (Marcus et al., 2012). Benefits extended to family and friends accompanying patients in the AAI group with improvements in emotional distress and feelings of well-being. The same authors replicated the study with fibromyalgia patients and again found improvement in pain, mood, and emotional distress in those choosing to wait in the room with the dog compared with a control group not waiting in a room with a dog (2013).

Investigating the effect of AAI on children attending an outpatient obesity program, researchers conducted a small, randomized crossover study comparing exercise performance, motivation, well-being, and satisfaction in children in the presence of a therapy dog and a human (Wohlfarth, Mutschler, Beetz, Kreuser, & Korsten-Reck, 2013). Children in the dog present condition were reported to have less passive behavior and increased physical activity compared with the human present condition. No significant differences were found on the subjective measures of motivation, well-being, or satisfaction. As a non-invasive, safe, and low-cost intervention, the use of AAI represents a desirable approach to improve the patient experience during outpatient procedures; however, more rigorous research is needed to determine efficacy with different patient populations.

To our knowledge, AAI has never been implemented during outpatient cystoscopy. Given its efficacy profile detailed above, AAI may represent a greatly underutilized tool with the potential to alleviate the distress associated with outpatient cystoscopy. The primary study aim was to investigate the effect of a single AAI on changes in patient systolic blood pressure (SBP), heart rate (HR), and self-reported fear, anxiety, and stress prior to outpatient cystoscopy and self-reported pain after cystoscopy. A secondary aim was to assess the effects of gender, age, attitudes toward dogs, and previous cystoscopy on study outcomes. Gender has been documented as moderating the effect of pet ownership on anxiety and depression in previous studies (Barker et al., 2018; Tower & Nokota, 2006), and therefore may be a significant moderating variable in this study. Less is known about differential effects of pet attitudes or AAI on different adult age groups. Since adults undergoing cystoscopy include individuals from young adulthood to the elderly, the authors wanted to control for any differential age effects. Relatedly, AAI may be more beneficial for some individuals and clinical populations than others (Casciotti & Zyckerman, 2018), and attitudes towards the species involved in AAI may potentially identify those more likely to benefit. The authors also thought that previous experience undergoing cystoscopy might influence anxiety, fear, and stress related to the procedure. Therefore age, attitudes toward dogs, and prior cystoscopy were included as potential covariates. The study protocol was approved by the senior author's university institutional review board and exempt from IACUC review.

Method

A prospective randomized control design was used in which consented participants were assigned to the 15-minute AAI session or 15-minute control session prior to their cystoscopy procedure.

Participants

A sample size of 87 was determined by power analysis using data from a previous study (Barker et. al., 2010) to detect a difference in HR, with 80% power between intervention and control groups. Oversampling (n=95) was conducted to account for participants not completing the study. Patients were recruited over an 18-month period in an outpatient urology clinic of an academic medical center with those recommended for cystoscopy invited to participate.

AAI and Control Sessions

AAI involved a 15-minute visit with the participant in a private, pre-procedure room by one of 10 certified therapy dogs and its owner, experienced members of the medical center's therapy dog program meeting strict criteria for hospital visitation. Participant interactions included petting the dog, speaking with the handler, and/or watching the dog perform tricks. Therapy dogs participating in the study included male and female pure and mixed breed dogs of varying sizes, including an Australian Shepherd, Pomeranian, Golden Retriever, and Goldendoodle. Therapy dog teams were registered with either Pet Partners or Alliance of Therapy Dogs, had completed the medical center's strict orientation program, and followed manualized program procedures consistent with The Society for Healthcare Epidemiology of America (SHEA) guidelines for animals in healthcare facilities (Murthy et al., 2015). The dog handler followed study guidelines avoiding any discussion of the patient's medical condition, treatment, or upcoming procedure. The control condition involved waiting in the pre-procedure room for 15 minutes with access to the use of smart phones, tablets, and reading material per usual protocol.

Flexible Cystoscopy

Flexible cystoscopy was performed in the standard fashion. Two percent viscous lidocaine was inserted per urethra for local anesthetic, and cystoscopy was performed using the 15 French Karl Storz 11272CU1 flexible cystoscope.

Measures

Physiological Stress. SBP and HR were collected as physiological stress indicators using the standard clinic equipment, a Welch Allyn vital signs monitor 6000 Series. The monitor is calibrated and checked by the medical center's Clinical Engineering Department at least once each year.

Fear, anxiety, pain, and stress. Single item Visual Analog Scales (VAS) were used to assess immediate perceived fear, anxiety, pain, and stress. Each VAS consists of a 150 mm line anchored at either end by "None" and "Most severe imaginable." Written instructions state, "Check along the scale below to indicate the level of (stress, fear, pain, anxiety) you are feeling right now." Visual analog scales are widely used self-report measures with acceptable reliability and validity in assessing a wide range of health outcomes including pain (Ahles, Ruckdeschel, & Blanchard, 1984) , anxiety (Barker et al., 2003), feelings (Aitken, 1969), and mood (Ahearn, 1997).

Coleman-Dog Attitude Scale. (C-DAS; Coleman, Green, Garthe, Worthington Jr, Barker, & Ingram, 2016). The C-DAS is a 24-item scale developed to assess attitudes toward dogs. A 5-point Likert scale, ranging from "strongly disagree" to "strongly agree," is used to rate agreement with a series of statements about dogs. Acceptable validity and reliability have been demonstrated (Coleman et al., 2016). Cronbach's alpha for our sample was 0.94 overall with individual items ranging from 0.94 to 0.96.

Procedures

At a regularly scheduled appointment, patients were evaluated by a physician for their medical condition in an outpatient urology clinic. If cystoscopy was indicated, a member of the research team discussed participation in the study and screened interested patients for eligibility. Inclusion criteria were age 18 or older, English speaking, and able to provide informed consent. Exclusion criteria were dog fears, dog allergies, and transplant or incarcerated patients. Eligible participants completed informed consent, completed initial assessments, and were randomly assigned to the treatment or control conditions using sealed envelopes. Randomization was computer-generated by the study statistician. Prior to enrollment, participants and researchers were blinded to study conditions. Initial assessments included a brief demographic survey (age, gender, prior-cystoscopy, indication for cystoscopy) and the C-DAS.

On the day of the cystoscopy procedure, participants were gowned, prepared, and brought to the pre-procedure room. Study personnel collected SBP and HR and administered the anxiety, fear, and stress VAS scales (Time 1). Participants then participated in the AAI or control session in the pre-procedure room for 15 minutes. Immediately following the session, study personnel collected the same outcome measures (Time 2). The participant then underwent cystoscopy. Following the procedure, the same outcome measures were again collected (Time 3) in the post-procedure room. A pain VAS was also collected at Time 3 to assess any perception of pain from the cystoscopy procedure.

Statistical Analyses

Descriptive statistics were computed for the outcomes of SBP (mmHg), HR (ppm), and VAS scores (mm) for anxiety, fear, and stress at study time points 1 (Time 1: Pre-Treatment/Pre-cystoscopy), 2 (Time 2: Post-Treatment/Pre-cystoscopy) and 3 (Time 3: Post-Treatment/Post-cystoscopy), VAS pain at Time 3, and general patient characteristics (means and standard deviations for age and C-DAS score and frequency counts and percentages for gender and prior cystoscopy procedures). General linear models were used to examine the effects of treatment (AAI versus control), gender (male versus female), and their interaction on the change for each of the response variables between time points (Kutner, Nachtsheim, & Neter, 2004). In these models, age, C-DAS, and previous cystoscopy were included as covariates. Least square means were computed and tested to quantify the extent of any significant differences among the gender, treatment, and gender by treatment effects. Bonferroni corrections for multiple comparisons were considered for testing between the levels of any significant gender by treatment effect. Since pain was collected only Post-cystoscopy at Time 3, a general linear model was used to test for significant differences in pain between treatment groups and gender, including age, C-DAS, and previous cystoscopy as covariates. Reliability and validity for the VAS scores were assessed in a similar manner as that found in Barker et al. (2003) in which correlations and corresponding *p*-values between the Pre/Post-Treatment difference in VAS score (Time 1 to Time 3) and the pre-intervention (Time 1) score were computed. All statistical testing was conducted in SAS v9.3 with an alpha of $p=0.05$ level of significance.

Results

Participant demographics

Ninety-five participants (55 males [57%] and 40 females [42%]) were enrolled in the study and randomly assigned to the intervention (n=45) or control (n=49) condition. Most had no prior cystoscopy procedure (n=74, 77%). Average participant age was 55.49 years (SD=14.55, range=20-83) and average C-DAS score was high (mean=95.11, SD=19.13). All but two participants received the allocated intervention – one refused on the study day and the other was scheduled at a non-intervention time. One participant allocated to the control group changed doctors and did not complete the control condition. Data from five additional participants (one intervention and four control) were not analyzed due to incomplete data collection forms. Therefore, analysis

Table 1. Descriptive Statistics for main variables by Animal-assisted Intervention (AAI) and control groups

Variable		Time 1		Time 2		Time 3		Change Time 1-Time 2		Change Time 1-Time 3		Change Time 2-Time 3
AAI	N	M ± SD	N	M ± SD	N	M ± SD	N	M ± SD	N	M ± SD	N	M ± SD
SBP	43	134.42 ± 15.90	42	136.36 ± 13.29	44	140.77 ± 16.06	42	2.05 ± 13.37	43	5.81 ± 14.11	42	3.79 ± 11.24
HR	43	76.56 ± 14.90	43	77.81 ± 20.47	44	73.68 ± 13.19	43	1.26 ± 16.93	43	-3.44 ± 8.91	43	-4.70 ± 15.90
Anxiety VAS	43	62.51 ± 46.48	43	49.30 ± 47.85	44	26.91 ± 37.70	43	**-13.21 ± 29.27***	43	-37.77 ± 44.80	43	-24.56 ± 44.86
Fear VAS	43	55.53 ± 45.78	43	48.49 ± 46.97	44	17.75 ± 31.36	43	-7.05 ± 38.54	43	-39.47 ± 41.43	43	-32.42 ± 40.35
Stress VAS	43	65.47 ± 46.59	42	49.33 ± 41.07	44	25.00 ± 37.54	42	**-17.67 ± 23.55***	43	**-42.33 ± 44.64***	42	-25.69 ± 35.46
Pain* VAS	-	-	-	-	44	42.95 ± 42.24	-	-	-	-	-	-
Control												
SBP	42	136.17 ± 19.75	42	135.98 ± 20.83	42	138.45 ± 20.83	42	-0.19 ± 16.15	42	2.29 ± 15.03	42	2.48 ± 13.45
HR	42	76.00 ± 16.45	42	74.76 ± 14.08	42	75.19 ± 14.67	42	-1.24 ± 7.89	42	-0.81 ± 7.64	42	0.43 ± 8.44
Anxiety VAS	43	54.65 ± 42.89	42	58.29 ± 46.69	42	27.50 ± 37.15	42	4.12 ± 21.06	42	-26.67 ± 41.80	42	-30.79 ± 39.74
Fear VAS	43	46.09 ± 47.90	42	44.00 ± 48.33	42	18.21 ± 32.73	42	-8.81 ± 13.86	42	-26.67 ± 47.13	42	-25.79 ± 46.55
Stress VAS	40	49.53 ± 44.35	42	44.86 ± 45.83	42	26.31 ± 36.22	40	-29.25 ± 21.33	40	-22.08 ± 35.32	42	-18.55 ± 36.48
Pain[1] VAS					41	36.24 ±35.39	-	-	-	-	-	-

[1]Pain VAS only collected at Time 3
Note. SBP – systolic blood pressure (mmHG); HR – heart rate (ppm); VAS – Visual Analog Scale (mm);
SD – standard deviation; Time 1 – Pre-treatment/Pre-cystoscopy; Time 2 – Post-treatment/Pre-cystoscopy;
Time 3 – Post-treatment/Post-cystoscopy
*Change in VAS scores was statistically significant in general linear model including effects of gender, Age, C-DAS, and prior cystoscopy, p-value<0.05.

was conducted on data available from 87 participants. Only one outlier was removed for a participant whose SBP was elevated by 60-70 mmHg at Time 2 as compared to Times 1 and 3. Upon further scrutiny, the value at Time 2 was determined erroneous and marked as missing data. Correlations between the Pre/Post-Treatment differences (Time 1 to Time 3 and the pre-treatment (Time 1) score for VAS scores of anxiety, fear, and stress were 0.65 ($p<0.01$); 0.78 ($p<0.01$); and 0.70 ($p<0.01$) respectively, indicating that the scores reported by the patients on the VAS scales were not randomly marked, supporting the validity of the VAS.

Treatment Effects

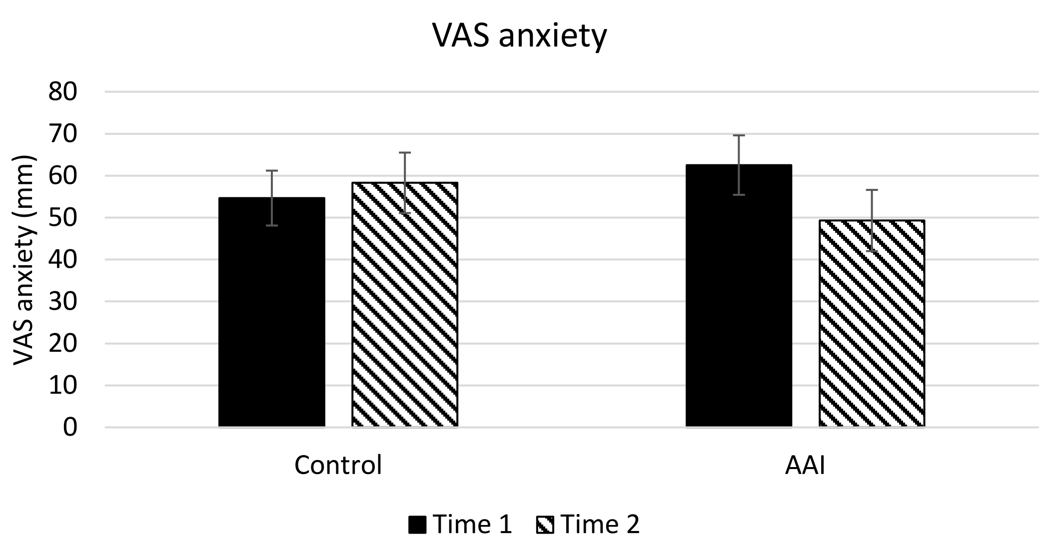
Table 1 provides general descriptive statistics for SBP, HR, anxiety, fear, pain, and stress, by treatment group for each data collection time point as well as the change between time points. General linear models were fit separately to compare treatment effects on the change in SBP, HR, anxiety, fear, and stress levels between Times 1 and 2, Times 2 and 3, and Times 1 and 3.

Change in SBP. There were no significant effects of any variables on SBP when examining the change from Time 1 to Time 2 (df=1,72; *F*=1.81, *p*=0.11), the change from Time 2 to Time 3 (df=6,72; *F*=1.44, *p*=0.21), or the change from Time 1 to Time 3 (df=6,73; *F*=2.09, *p*=0.06).

Change in HR. Similarly, HR did not change significantly from Time 1 to Time 2 (df=6,73; *F*=0.98, *p*=0.44), from Time 2 to Time 3 (df=6,73; *F*=1.41, *p*=0.22), or from Time 1 to Time 3 (df=6,73; *F*=1.62, *p*=0.15), and was not impacted by gender, treatment, prior procedure, or C-DAS. A significant increase in HR was noted from Time 2 to Time 3 with increasing age associated with higher HR (df=1,73; *F*=4.37, *p*=0.04).

Change in Anxiety. Figure 1 plots the observed anxiety scores for Time 1 and Time 2 by treatment group. Modeling results demonstrated that participants in the AAI group experienced a significant decrease in VAS anxiety score from Time 1 to Time 2 as compared to the control group (df=1,73; *F*=7.93, *p*=0.01). In general, participants in the control group experienced a slight increase of 1.49 mm on average in anxiety scores (95% CI: -8.95, 11.93 mm), whereas those participants in the AAI group experienced a decrease in VAS anxiety on average of 15.33 mm (95% CI: -25.22, -5.43 mm). In addition, there were significant increases on average in the change in anxiety

Figure 1. Average VAS Anxiety Score by Treatment Group at Time 1 and Time 2*



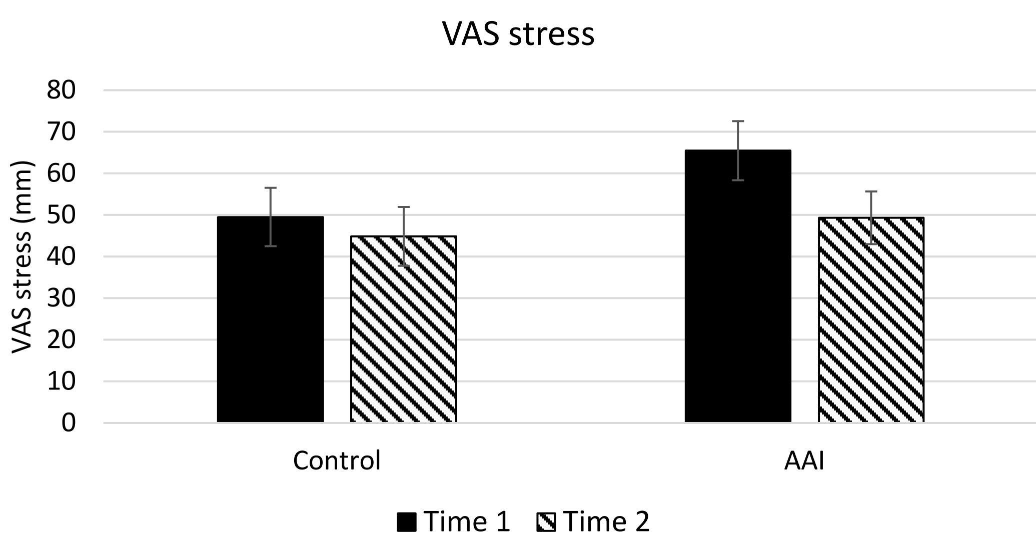
*Time 1 – Pre-treatment/Pre-cystoscopy; Time 2 – Post-treatment/Pre-cystoscopy; Time 3 – Post-treatment/Post-cystoscopy. There is a significant difference in the change from Time 1 to Time 2 between Control and AAI in which VAS anxiety increases slightly in Control and decreases in AAI from Time 1 to Time 2.

scores from Time 1 to Time 2 as age increased (df=1,73; *F*=4.30, *p*=0.04). For each additional year of age, the change in anxiety increased by 0.43 mm on average ($\beta = 0.43$, se=0.21). There were no significant effects of any variables between Time 2 to Time 3 (df=6,73; *F*=0.43, *p*=0.85) or from Time 1 to Time 3 (df=6,73; *F*=0.82, *p*=0.56). There were no significant effects of gender, attitudes toward dogs, or previous cystoscopy on anxiety changes between any time points.

Change in VAS Fear. There were no significant effects of any variables on fear when examining the change from Time 1 to Time 2 (df=6,73; *F*=0.32, *p*=0.92), the change from Time 2 to Time 3 (df=6,73; *F*=0.58, *p*=0.74), or the change from Time 1 to Time 3 (df=6,73; *F*=0.86, *p*=0.53).

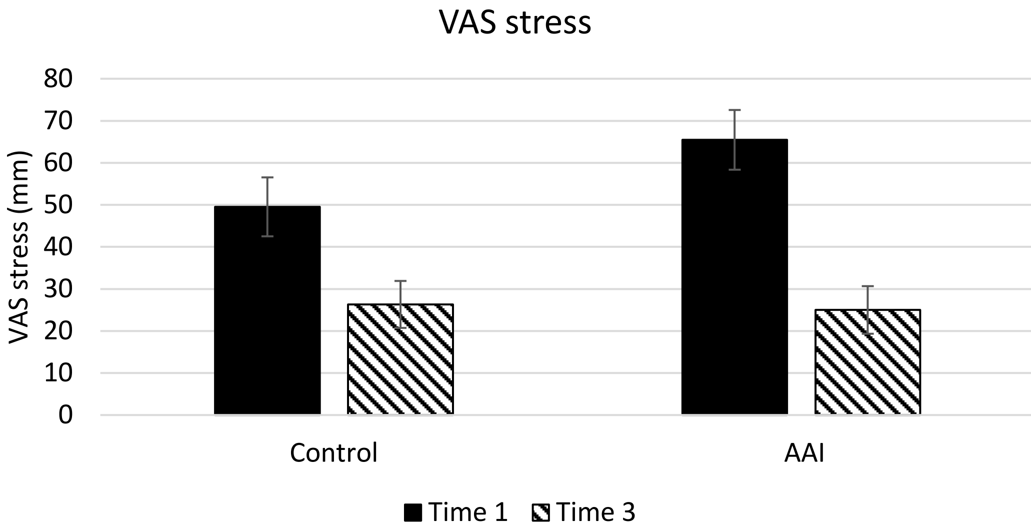
Change in Stress. Participants in the AAI group had significant decreases in stress scores from Time 1 to Time 2 (df=1,70; *F*=5.97, p=0.02) and from Time 1 to Time 3 (df=1,71; *F*=4.20, *p*=0.04). In addition, gender had a significant effect on stress scores from Time 1 to Time 2 (df=1,70; *F*=5.53, *p*=0.02) and from Time 1 to Time 3 (df=1,71; *F*=5.34, *p*=0.02). Figures 2 and 3 plot the observed stress scores by treatment group for Time 1 and Time 2 (Figure 2) and Time 1 and Time 3 (Figure 3). As shown in Figure 2 from Time 1 to Time 2, those in the AAI group experienced on average a significantly larger decrease in stress than those participants in the control group (AAI group: -18.39 mm, se=4.35; control group: -5.47 mm, se=4.61). Males experienced on average a significantly larger decrease in stress than females (males: -18.55 mm, se=4.54; females: -5.32 mm, se=4.62). Similarly, from Time 1 to Time 3 (Figure 3), those in the AAI group experienced on average a significantly larger decrease in

Figure 2. Average VAS Stress Score by Treatment Group at Time 1 and Time 2*



*Time 1 – Pre-treatment/Pre-cystoscopy; Time 2 – Post-treatment/Pre-cystoscopy; Time 3 – Post-treatment/Post-cystoscopy. There is a significant difference in the change from Time 1 to Time 2 between Control and AAI groups in which VAS stress decreases more for AAI than Control.

Figure 3. Average VAS Stress Score by Treatment Group at Time 1 and Time 3*



*Time 1 – Pre-treatment/Pre-cystoscopy; Time 2 – Post-treatment/Pre-cystoscopy; Time 3 – Post-treatment/Post-cystoscopy. There is a significant difference in the change from Time 1 to Time 3 between Control and AAI in which VAS stress decreases more for AAI than Control.

stress than those participants in the control group (AAI group: -46.42 mm, se=7.67; control group: -27.33 mm, se=8.16). Again, males experienced on average a significantly larger decrease in stress than females from Time 1 to Time 3 (males: -48.38 mm, se=8.01; females: -25.37 mm, se=8.21). There were no significant effects of any variables on stress from Time 2 to Time 3 (df=6,72; F=0.65, p=0.69). No other variables had a significant impact on changes in stress scores for any of the time point comparisons.

Differences in Pain. There were no significant differences in pain scores between the AAI and control group (df=1, 74; F=0.45, p=0.51). However, there were significant differences in pain scores between males and females (df=1,74; F=6.15, p=0.02). Using model estimated means, males, in general, had higher pain scores on average than females (Males: 53.84 mm, se=7.50; Females 30.61 mm, se=7.73).

Discussion

The primary purpose of this study was to assess the efficacy of a single, 15-minute AAI session in reducing patient fear, anxiety, pain, and stress associated with outpatient cystoscopy. SBP, HR, and VAS scores assessing anxiety, fear, and stress were assessed prior to and following the intervention immediately prior to cystoscopy, and following cystoscopy, controlling for patient age, gender, attitudes toward dogs, and history of prior cystoscopy. Pain VAS was also collected post cystoscopy. AAI had no significant impact on the change in SBP, HR, or VAS fear scores between any time points. However, there were significant differences between the AAI and control group in the changes in anxiety and stress scores. Patients who received AAI prior to cystoscopy had a significant decrease in anxiety and stress scores immediately following 15 minutes of AAI (Time 1 to Time 2) which were not demonstrated in the control group. These findings are consistent with other studies finding decreased anxiety (Barker & Dawson, 1998; Cole et al., 2007) and stress (Barker, Knisely, McCain, Schubert, & Pandurangi, 2010; Krause-Parello et al., 2016) associated with AAI.

Both AAI and control groups showed a decrease in stress scores from Time 1 to Time 3 (following cystoscopy), but the decrease was greater in patients who received AAI, providing a possible indicator of maintenance of AAI effects. Interestingly, significant gender differences were noted in stress scores between Times 1 and 2, and Times 1 and 3, with greater reductions seen in men regardless of whether they were in the AAI or control group. This may be partly due to the higher stress scores on average for males at Time 1 or may reflect an easement of patient stress about the procedure following education on expectations during and following cystoscopy.

No significant effect of AAI was found for self-reported pain following cystoscopy; however, significant gender differences were found with males reporting higher pain than females. This finding is consistent with other studies reporting higher pain levels in men following cystoscopy (Biardeau, Lam, Van Ba, & Corcos, 2017; Greenstein, A., Greenstein, Senderovich, & Mabjeesh, 2014). Overall, AAI prior to cystoscopy did not appear to effect pain after the procedure.

Attitudes toward dogs was not found to be a significant covariate on any of the outcome variables. These results may reflect the limited variability in the data with most participants scoring very positively on the C-DAS. Similarly, prior cystoscopy did not have a significant effect on any of the outcome variables. Familiarity with the cystoscopy by having experienced the procedure in the past did not reduce or heighten patient distress related to this procedure.

The lack of AAI effect on the physiological stress indicators is consistent with several other AAI studies conducted in health care facilities, including in psychiatric (Barker, Rasmussen, & Best,, 2003) and pediatric (Braun, Stangler, Narveson, & Pettingell, 2009; McCullough et al., 2017; Silva & Osorio, 2018) settings. Perhaps other factors inherent in the medical setting, such as the diagnostic or disease-related purpose of the visit, the sterile environment, or medical staff, influence the sensitivity of patients to possible physiological effects of AAI. Or, AAI in the outpatient clinic setting may not have the same effect on physiological stress indicators as it does on perceived stress. It is also possible that some of our lack of significant differences, especially for the physiological responses, could be due to sample size. We used data from a previous study comparing dog owners interacting with their own or an unfamiliar therapy dog in order to justify sample size calculations for this study of subjects undergoing cystoscopy (Barker et al., 2010). In that study, the observed changes in physiological responses (heart rate and blood pressure) were similar to that which we observed in this study; however, the standard deviations in this urology population were much higher. Accounting for these increased standard deviations in a future study may increase the sample size to a level that significant differences, if they exist, may be found. To that end, the values provided in Table 1 could be used by subsequent researchers to power such a study.

Further studies are needed to investigate the differences between physiological and psychological stress indicators related to AAI interventions. Our study has several limitations. For health reasons and patient privacy, the therapy dog teams were not allowed in the procedure room with the patient while the cystoscopy was being performed. It is possible that this mitigated some of the positive effects that the AAI may be able to provide, as patients were not able to have the positive distraction during the procedure itself. Additionally, VAS scores are patient-reported and are subjective measurements. Although objective measurements were included in this study, no effect of AAI was found on SBP or HR. Furthermore, by self-selecting to participate in a study involving dogs, patients with less favorable attitudes toward dogs may have opted out of participating, leaving the sample more biased to favorable outcomes. Therapy dog handlers followed their normal manualized procedures during the AAI interactions, with the addition of study guidelines to avoid any discussion of the patient's medical condition, treatment, or upcoming procedure and to adhere to a 15-minute visit limit. However, the intervention was not scripted, and participants did not receive identical interventions. The intervention represented the AAI interactions that are manually based, routinely occur in the medical center, and are evidence-based. Despite our limitations, we were able to demonstrate improvement in participant-reported anxiety and stress by participating in a brief AAI prior to outpatient flexible cystoscopy. The results contribute to the evidence base supporting benefits of AAI in clinical populations; however, further research is needed to identify the types of patients who will benefit most from AAI and under what circumstances.

The outpatient clinic in this study is part of a large academic medical center with a well-established therapy dog program based in the university's School of Medicine. Fully integrated into the medical center, the therapy dogs are well-known, very popular, and requested by most clinical departments. Therefore, the investigators did not encounter some of the barriers that other researchers may face in gaining entry to clinical settings since the therapy dog program is considered a complementary therapy. Key strategies for gaining medical personnel acceptance of our therapy dog program included the development of strict policies and procedures with involvement of key medical, nursing, and administrative personnel; widespread education on the evidence base supporting AAI; and involvement of physician and nurse researchers in efficacy studies. Resources are available to assist other health care facilities in establishing similar programs (Barker et al., 2019).

Conclusion

While minimally invasive, outpatient cystoscopy is still associated with patient fear, anxiety, pain, and stress. There are few effective techniques available for improving these patient parameters before, during, and after this procedure. AAI has been shown to improve physiologic and psychologic parameters in some health care settings. To our knowledge, this is the first study to assess the impact of AAI on patient distress during outpatient flexible cystoscopy in a prospective randomized fashion. Although no effect was found on physiological stress indicators, we demonstrated significant improvement in patient-reported anxiety and stress associated with flexible cystoscopy following AAI. AAI is a low-cost, noninvasive intervention without side effects with the potential to complement existing therapies in reducing patient distress related to medical procedures. Additional research is needed to determine whether the use of AAI is widely applicable and beneficial in outpatient procedural settings.

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