Beneficial effects of animal-assisted visits on quality of life during multimodal radiation-chemotherapy regimens

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Background Animal-assisted visits (AAVs) are commonplace in cancer centers, but there is little evidence of their usefulness. **Objective** To test the efficacy of AAVs in improving the quality of life in patients with head and neck cancer receiving combined chemotherapy-radiation therapy.

Methods 42 patients consented to daily AAVs during the time they received therapy for head and neck cancer. The Functional Assessment of Cancer Therapy-General Scale (FACT-G) was administered at baseline, week 3, and week 7 (at the end of therapy), and the Satisfaction With The AAV Intervention instrument, an 18-item scale adapted from the Pet Attitude Scale.

Results 37 patients completed at least baseline and 1 follow-up assessment for a single group analysis of change over time. Means for FACT-G subscales showed significant declines in Physical Well-Being (PWB, P < .001) and Functional Well-Being (FWB, P = .003). In contrast, Social Well-Being increased (SWB, P = .03). Controlling for declines in PWB at each time point, increases in Emotional Well-Being (EWB) were also significant (P = .004).

Limitations Scheduling and patient preference prevented conducting a randomized trial.

Conclusion FACT-G analysis showed significant increase in SWB and EWB despite high symptom burden and clinically evident and expected declines in PWB and FWB. Mean scores for satisfaction related to psychological symptoms, liking animals/pets, and contact with animals were consistently higher than neutral score or *Unsure* (all P < .001). Satisfaction related to physical symptoms was not significantly different from neutral. Though self-selected for an affinity to pets, patients endorsed a high level of satisfaction, which supports the usefulness of the intervention.

Funding Grant from the Good Dog Foundation and Pfizer Animal Health (now Zoetis Animal Health)

he first documented study of the relationship between animals' positive impact on L human health and well-being took place in the 18th century at The York Retreat, a psychiatric facility started by Quakers in York, England, where residents wandered freely around courtyards stocked with animals and birds.1 As the emphasis turned to scientific methods in medicine and psychology, the animal-human bond was of little interest to researchers, although at the Army Air Corps Convalescent Home in Pawling, NY, patients recovering from war experiences were encouraged to work with farm animals.² A 1980 study of 92 patients discharged from a cardiac care unit found that pet owners had an increased 1-year survival rate.³ Contact with animals has been shown to lower blood pressure,^{4,5,6} reduce anxiety,7 decrease depression,8 and reduce pain perception in children.9

In a randomized, repeated-measures study of 76 adults,¹⁰ investigators compared systolic pulmonary

artery pressure, pulmonary capillary wedge pressure, and epinephrine and norepinephrine levels in 3 groups: 1 that received a 12-minute visit from a volunteer with a therapy dog; 1 that received a visit from an unaccompanied volunteer; and a control group that received the standard care. After the intervention, the volunteer-dog group had the greatest decreases in all areas.

In a 2008 study by Morgan and colleagues, 141 randomly selected undergraduates were given an anxiety-provoking public-speaking task and then exposed to interaction with a therapy dog and handler team, a friendly person, or no human or animal interaction. After administering the State Trait Anxiety Inventory (STAI), the researchers wrote that patients who had interacted with the therapy dog and handler team reported significantly lower levels of anxiety compared with those who had interacted with a person alone or who had no interaction at all.¹¹ Findings from a pre- and posttreatment

Accepted for publication July 9, 2014. Correspondence: Stewart B Fleishman, MD; stewartbf54@gmail.com. Disclosures: The authors have no disclosures. †Now part of the Mount Sinai Health System. JCSO 2015;13:22-26. ©2015 Frontline Medical Communications. DOI 10.12788/jcso.0102.

crossover study of 230 hospitalized psychiatric patients that compared the effects of animal-assisted therapy sessions with therapeutic recreation sessions showed a significant reduction in anxiety scores in the animal-assisted therapy group.¹² The benefits of animal-assisted therapy (AAT) in cancer patients was first documented in a 1984 study¹³ in which 15 terminally ill cancer patients received weekly 90-minute sessions with visiting dogs for 10 weeks and showed decreased anxiety and despair. In the two and a half decades since the latter study, many hospitals have welcomed animals, primarily dogs, into their recreational or complementary and alternative medical programs.

One of the problems in studying the effects of AAT on cancer patients is the difficulty of measuring patient responses to the intervention. In a longitudinal study of 30 adults who were beginning nonpalliative (first-line) radiation therapy for cancer, patients were randomly assigned to a dog visit group, friendly human visit group, or quiet reading group.14 Data was collected using a demographic questionnaire, the Profile of Mood States, the Orientation to Life Questionnaire, and a self-perceived health questionnaire. Mood, sense of coherence, and self-perceived health were assessed at baseline and at the last session. In all 3 groups, levels on tests decreased after radiation therapy, and no statistically significant differences were found between groups in mood or sense of coherence, although patients all 3 of the groups considered their experiences positively and said they would recommend the intervention to other patients. The authors concluded that identifying proper outcome measures, identifying a true control intervention, and determining an adequate sample size were important for future studies.

The present study evaluates the efficacy of AAVs in cancer patients receiving intensive multimodal concomitant radiation therapy and chemotherapy. The primary objective is to assess the impact of certified therapy animal-assisted visits (AAV) on quality of life during multimodal treatment for head and neck and gastrointestinal (GI) cancers by using a validated and reliable quality-of-life assessment that is routinely used in cancer clinical trials. Patients' satisfaction with the intervention of an AAV during cancer treatment was measured with a self-assessment tool adapted from the Pet Attitude Scale. Patients' qualitative views of the AAV were collected as well.

Methods

Patients were eligible for the study if they were receiving combined chemotherapy and radiation therapy for cancer at Beth Israel Cancer Center in New York, were open to receiving AAVs, and had the ability to sign informed consent and complete the various quality of life forms in either English or Spanish. Those with significant dog allergies, dislike of dogs, or an aversion to or fear of dogs were excluded from participation. All of the therapy dogs in this study were trained by, certified with, and provided under the auspices of The Good Dog Foundation, a New Yorkbased organization that promotes animal-assisted therapy.

Patients who were starting multimodal concurrent radiation therapy and chemotherapy for head and neck cancer or GI cancers were recruited at the time of initial consultation or treatment planning visits. Patients who agreed to participate signed an IRB-approved informed consent. Demographic and clinical data (disease staging, planned treatment, comorbidities, medication lists) were obtained from the patient's medical record.

The FACT-G questionnaire (core questions) for measuring quality of life was completed at baseline. The patients met their certified therapy dog during an AAV on the first day of treatment. Dogs were bathed and groomed before visits. Dog handlers wiped the dog's paws before entering the waiting room. The health and safety policies of The Good Dog Foundation were followed at all times.

An AAV was scheduled for each radiation therapy treatment or chemotherapy appointment. More than one AAV and certified therapy dog team was assigned to each patient so that a team would be available each day that radiation was scheduled. The daily visit took place in the radiation therapy waiting areas, the chemotherapy suite, or the hospital room. During the visits, the patient and dog interacted in the usual ways, by petting, talking, and playing. It was expected that other patients in the waiting area would also interact with the therapy dogs.

The FACT-G scale is a widely used valid and reliable scale for measuring cancer-related quality of life in clinical trials. It consists of a 27-item core or general module (FACT-G) with items common to all patients treated for cancer. The FACT-G items consist of 4 subtests: Personal Well-Being (PWB), Social Well-Being (SWB), Emotional Well-Being (EWB), and Functional Well-Being (FWB). Additional modules for specific cancer sites measure symptoms and treatment effects specific to each type of cancer. Because of the nonhomogeneous nature of the cancers and conditions in the patients in this sample, only the core module was used to evaluate the AAV program. A change of more than 2 points on any subscale of the FACT-G is considered clinically meaningful.

The Satisfaction With The AAV Intervention instrument used in this study is an 18-item scale that was adapted from the Pet Attitude Scale, and a treatment satisfaction scale used in a previous cooperative group study.^{15,16} It was administered biweekly to assess patients' motivation to come to appointments; their tolerance of waiting times; their ability to withstand treatment experience; the effects of the AAV on nausea and pain; the lingering effect of the dog visit after leaving treatment for the day; and the patient's perception of social support owed to the vol-

TABLE 1 Patient characteristics (N = 37)	
Characteristic	No. of patients, n (%)
Mean age, y (SD): 57.2 (8.44)	_
Male gender	25 (68)
Race/ethnicity White Hispanic Black Asian	21 (57) 8 (22) 6 (16) 2 (5)
Cancer site Oropharynx Hypopharynx Esophagus Laryngopharynx Nasal cavity	23 (62) 4 (11) 3 (8) 2 (5) 2 (5)
Cancer stage 2 3 4	1 (3) 6 (16) 30 (81)
Chemotherapy toxicity° High Moderate Low	27 (75) 3 (8) 6 (17)
Resection before baseline	13 (35)
Comorbid conditions Hypertension Hypercholesterolemia Diabetes Asthma HIV	11 (30) 7 (19) 3 (8) 3 (8) 2 (5)
High = any cisplatin or TPF (docetaxel+cisplatin+f	luouracil); Moderate = car-

°High = any cisplatin or IPF (docetaxel+cisplatin+tluouracil); Moderate = carboplatin, taxol+carboplatin; Low = erbitux, 5-FU (fluorouracil)

unteer, the dog, or both. Each question in the satisfaction scale was rated on a 7-point Likert-type scale ranging from 1 (not satisfied) to 7 (extremely satisfied). A factor analysis of the questions indicated that there were aggregated underlying satisfaction factors: help with psychological symptoms (Psychological); help with physical symptoms (Physical); generally liking animals/pets (Like Animals); and positive attitudes toward close personal contact with animals (Contact with Animals). Satisfaction was assessed only after the patient had experienced the AAV. Each factor was scored by calculating the mean over all items in the scale so the possible range for each scale score was 1 to 7.

Normally distributed data (eg, age) were described in terms of mean and the standard deviation, and categorical data (eg, ethnicity) were described in terms of frequency (%). Outcome data were analyzed using linear mixed model regression to compare changes in the FACT-G and in satisfaction over time for all patients with a baseline and at least 1 follow-up measurement. To test for the effect of an AAV in this population, it was estimated that 41 participants would have been necessary to have 80 % power to detect a clinically meaningful difference of points with regard to emotional well-being (EWB), with a standard deviation of 4.5 based on published norming data for the FACT-G.

Results

About 100 patients were approached to participate in the study, and 42 signed informed consent. Of the 42 consented patients, 37 had a least a baseline and 1 follow-up measurement. Table 1 shows the basic characteristics of the 37 patients who were included in the intent-to-treat (ITT) analysis. Their mean age was 57 years, and most (68%) were male. Ethnicity patterns as shown in Table 1 were similar to the general patient population of the hospital reflected in nonclinical trial practices. As a tertiary care facility with a center of excellence in head and neck cancer treatment, patients came to Beth Israel from local areas as well as other US cities and internationally, specifically for treatment. Most of the patients were being treated for oropharyngeal cancer (62%), and 81% of patients had stage 4 disease. In all, 30% were hypertensive, and 19% were hyperlipidemic. The mean duration of each visit was 15 minutes, and there were a mean of 18 visits per patient.

The mean scores for the subscales of the FACT-G at baseline (week 0), week 3, and week 7 are shown in Table 2. Patients underwent marked and significant declines in PWB (overall P < .001) and FWB (overall P = .003). In contrast, SWB showed a significant increase (overall P = .03; P baseline vs week 3 = .02; baseline vs week 7, P = .04). This increase was not clinically meaningful, however. The means for EWB also showed small increases over time, which were not significant when time was analyzed by itself. After controlling for declines in PWB at each time point, the increases in EWB were both statistically significant (overall P = .004) and clinically meaningful.

Table 3 shows the mean scores for each satisfaction factor. There were no significant changes in satisfaction over time between first and last administration. The overall magnitude of the means for the Psychological, Like Animals, and Contact with Animals scales were all significantly higher than 4, which would be considered Neutral or Unsure, all P < .001 at first and last administration. In contrast, the mean scores for Physical were not significantly different from a neutral score of 4 at either first or last administration.

Discussion

An analysis of the responses to the FACT-G shows a statistically significant and clinically meaningful increase in Emotional Well-Being (EWB) in the face of clinically evident and expected declines in Physical Well-Being (PWB)

	Week			Р	
Subtest	0 (N = 40)	3 (n = 24)	7 (n = 16)	0 vs 3	0 vs 7
PWB ^{ab}	21.38 (7.15)	16.79 (6.29)	14.88 (6.50)	< .001	.009
SWBab	22.82 (5.94)	22.92 (3.49)	23.25 (2.91)	.02	.04
EWB ^{cd}	17.38 [17.07] (5.67)	18.58 [19.03] (4.52)	18.50 [19.52] (4.37)	.28 [.01] ^d	0.39 [.003]ª
FWBab	17.22 (7.84)	13.54 (5.17)	11.69 (7.14)	< .001	< .007

°Mean (SD). ¹7 items, score range = 0-28. ^cMean [Mean after controlling for PWB] (SD). ⁴6 items, score range = 0-24. ⁴P after controlling for PWB

and Functional Well-Being (FWB). Because of the high symptom burden for patients receiving concurrent radiation therapy and chemotherapy, we sought a creative intervention that could be easily replicated at cancer centers nationally and internationally. Confirmation of the value of AAVs to patients receiving multimodal cancer treatment justifies the formation of community cancer center partnerships to make the use of AAVs a viable option.

The Satisfaction With the AAV Intervention assessment further supports the utility of the AAV intervention. The items are clustered in 2 areas: patient affinity for animals as pets and patient satisfaction with the use of AAVs as an intervention during multimodal cancer treatment. Patients who enrolled in the study had self-selected to participate, so it was predictable that their attitudes toward pets would be high from the start. Data analysis showed that such an affinity was sustained throughout the intervention. Responses to the items about the helpfulness of the AAVs during treatment showed improvement throughout their period of treatment and remained high at the end of the intervention. These responses further confirm the usefulness of AAVs in this treatment setting.

Nonscientific qualitative responses to the intervention focused on 2 areas: the unconditional love that pets were seen as providing and the friendly dedication on the part of the pet owners. One patient was quoted saying, "Every dog visited me in the past few treatments and makes me feel good. It is such a good program." Another patient had suggested that the AAVs be extended to others outside of the study: "This is such a great thing, it should be offered to everyone in the waiting room, not just to individual patients."

As patients became increasingly uncomfortable over the course of radiation therapy, experiencing pain, fatigue, skin lesions, and the inability to eat, swallow solid food, or to speak, the therapy dogs remained happy to see them, not seeming to notice any alteration in appearance. Patients also commented on the value of the human visitors. One patient said that she greatly looked forward to and relied on the support she received from the owners of the therapy dogs, but said, "People couldn't have just come alone without their dogs - that would have been awkward and silly." Another patient stated, "I greatly benefited from the presence of the dogs. They dispelled my worries while I was waiting for my treatment." A few patients reacted so positively to the AAVs that they continued to remain in contact with the visitors even after their participation in the program had ended. Such positive outcomes were especially meaningful in the context of this study.

The study's limitations grew out of the practical considerations of scheduling AAVs 5 days a week for 6 weeks,

Subtest ^{ab}	Order of administration		<i>P</i> (H ₀ : msean > 4.0)	
	First (n = 34)	Last (n = 25)	First	Last
Psychological	5.85 (1.12)	6.00 (1.01)	< .001	< .001
Physical	3.57 (1.64)	3.53 (1.45)	.14	.12
Like Animals	6.08 (1.32)	6.10 (1.04)	< .001	< .001
Contact with Animals	5.87 (1.37)	6.23 (1.23)	< .001	< .001

taxing the commitment of even the most energetic and motivated human members of the AAV dyad. Radiation therapy centers struggle with the expectable technical delays that come with working with sensitive equipment, which often resulted in the AAV team being on time but a patient receiving a delayed treatment time, after the AAV team was scheduled to leave. Most of the AAVs were scheduled for before the handler's work day started so the handler needed to leave time to take the certified therapy dog home in order to be at work on time, and that precluded them from being able to remain late when the equipment took longer than expected to service.

Additional practical concerns in implementing the AAVs were related to the vagaries of mass transit and traffic delays, which affected patients' arrivals at our multisite cancer center, which is located in the congested area of Manhattan in New York City. Inevitable lateness due to delays in the public bus or subway transit systems prevented patients from completing all the scheduled AAV visits. Delays in the on-time arrival of ambulette or van services further hampered AAV team and patients from being in the same place at the same time. Anticipated inclement weather in the northeast portion of the United States added an additional stress on the scheduling.

These delays extended the study's completion over many more months than expected, which placed an additional burden on the largesse of the AAV handlers. The AAV teams did have the capacity to visit more than 1 patient each time they brought their therapy dogs to the cancer center, thus extending each team's capabilities. Future studies could examine whether AAVs have their greatest impact on ambulatory or inpatient care, or whether its impact is more prominent with certain types of cancer or treatment modality. The inability to blind or randomize arms of a study with or without AAVs is driven by patient preference and their concern about allergic reactions to the dogs.

These study-related procedural obstacles are much less likely to be impediments to a clinical program, which would not have to adhere to the kind of strict scheduling guidelines a research study requires or to evaluate outcomes, where uniformity is vital. Having had AAVs off-study in the infusion suites at our cancer center over many years has shown that patients and staff wholeheartedly welcome the visits, without the concern about the standardization that was necessary for this study. AAVs freely relate to many patients, to visitors accompanying patients, and to staff members. This anecdotal evidence is confirmed by this study's findings. Cancer centers that are considering adopting an AAV program should not be deterred by the obstacles encountered in the standardization of the procedures for this study. AAVs add a valuable element to the environment of care for patients receiving multimodal cancer treatment. Their significant effect on emotional well-being in the face of the moderate to high symptom burden in this cancer patient population is consistent with the utility of AAVs for patients with other medical comorbidities. A more widespread presence in cancer treatment centers should be encouraged.

Acknowledgments

This paper was presented as a poster at the 2013 American Psychosocial Oncology Society annual meeting.

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