HTVET

HT Vista Validation Report – Israel

November 2021 - May 2022

HT Vista Introduction

The HT Vista system is a non-invasive, heat diffusion imaging system that differentiates benign from malignant cutaneous and subcutaneous masses in dogs. The underlying principle of the HT Vista technology is that normal and malignant tissues display different heat transfer rates due to differences in composition, metabolism, tissue morphology, and vascular network, which affect their thermophysical properties.

The HT Vista System in Clinical Setup

The system is composed of a control unit that includes a mini personal computer with internet capability, a touch screen, a dedicated software application, and a handheld probe. The probe consists of an optical camera, a high-power LED (Light-Emitting Diode) emitter which serves as the heat source, and an inherent long-wave-infra-red (LWIR) video camera which records the thermal changes throughout the scan.

The HT Vista System

The Heat Diffusion Imaging (HDI) process starts with a one-minute scan of the suspected mass. During the scan, the thermal camera continuously records the tissue's temperature while the tissue is heated and then left to cool. The unique thermal signal produced during the scan is then processed in the HT's cloud using signal analysis and artificial intelligence (AI) algorithms to identify abnormal tissue. The results are immediately transmitted back to the device, classifying the tested mass as benign or malignant, enabling fast diagnosis and decision-making in the clinic.

Validation Background

Clinical validation was conducted at various community clinics in Israel as part of HT Vista's pre-commercial launch to the market in 2022. Its purpose was to validate the system’s performance and determine the ability of the HT Vista to diagnose and distinguish between benign and malignant masses in dogs. This report focuses on the results obtained from 378 masses examined in dogs using the HT Vista v1.5.

Clinical Settings:

All scans were performed by Dr. Tali Buber, who is employed by HT Bioimaging LTD. Dr. Buber has visited over 40 community clinics across Israel and scanned over 500 dogs under a comprehensive validation study held by the company and the Israeli Veterinary Association. Every mass was scanned by the HT Vista and aspirated or biopsied. The HT Vista’s results are displayed on a scale of 1 to 10 (1-4: Malignant, 5-10: Benign). Then they were converted into a binary classification (malignant or benign) to compare them to the cytology or histopathology results and determine the algorithm performance [i.e., sensitivity, specificity, positive-predictive value (PPV), negative-predictive value (NPV), and accuracy].

Results

There were no reported safety or serious adverse events during the clinical pilot. Overall, a total of 378 scans were performed. Cytology was done in 347 cases, and histopathology was done in 31 cases.

Summary of the results obtained at the community clinics (GP) in Israel:

Table 1. Confusion matrix: malignant vs. benign classification by HT Vista in community clinics in Israel.

		HT Results		
		Malignant	**Benign**	**Total**
Cytology /Biopsy	**Malignant**	34 True Positive	6 False Negative	40
	Benign	103 False Positive	235 True Negative	338
	Total	137	241	**378**

Table 2. Performance metrics evaluation of the HT Vista in community clinics in Israel.

HT Vista Performance				
Sensitivity %	**Specificity %**	**Accuracy %**	**PPV %**	**NPV %**
85	70	71	25	98

Table 3. Types of scanned masses in Israel.

Malignant Tumors	Number of Cases	Correct Prediction by HT Vista
Carcinoma	2	2
Mast Cell Tumor	29	23
Soft Tissue Sarcoma (STS)	9	9
Total	**40**	

Benign Tumors	Number of Cases
Benign Epithelial cyst/tumor	87
Benign cutaneous Melanoma	2
Calcinosis circumscripta	1
Histiocytoma	2
Hyperplasia	3
Inflammatory process	16
Lipoma	226
Perineal Adenoma	1
Total	**147**

Discussion & Conclusions

The HT Vista algorithm was trained on more than 500 cases. This report focuses on additional 378 cases performed at the community clinics to the performance of the device. The results demonstrate an impressive ability of the HT Vista to differentiate between malignant and benign masses in dogs, with a sensitivity of 85% and an NPV of 98%. As the performance of the algorithm is based on AI and machine learning, the accuracy and sensitivity of the algorithm are expected to rise with additional scans performed. We suggest that the HT Vista system can be used in the clinic either as a first-line screening tool or as a decision support tool for every dermal and subcutaneous mass in dogs.

Appendix

The following list describes all types of tumors our HT Vista algorithm is trained to detect (more to be added during 2022):

Benign Lesions

•Adenoma, sebaceous adenoma

•Adnexal epithelial cyst/tumor, Epidermal cysts

•Basal cell tumor

•Benign cutaneous melanoma

•Cystadenoma

•Epithelioma

•Fibroma

•Hamartoma

•Hemangioma

•Histiocytoma

•Inflammatory lesions- panniculitis, steatitis, hyperplasia…

•Keratinous cyst

•Sebaceous cyst

•Lipoma

•Papilloma

•Trichoepithelioma

•Trichoblastoma

Malignant Lesions

•Adenocarcinoma

•Anal Sac Adenocarcinoma

•Carcinoma

•Cutaneous Hemangiosarcoma

•Subcutaneous Hemangiosarcoma

•Histiocytic sarcoma

•Mast cell tumor

•Malignant Melanoma

•Plasma cell tumor

•Round cell tumor

Terminology and Calculations

System performances are calculated according to the following formulas:

Sensitivity = TPR = $\frac{TP}{TP+FN}\ x\ 100$

Specificity = TNR = $\frac{TN}{TN+FP}\ x\ 100$

PPV = $\frac{TP}{TP+FP}\ x\ 100$

NPV = $\frac{TN}{TN+FN}\ x\ 100$

Accuracy = $\frac{TP+TN}{N}$

where,

TP	True Positive
TPR	True Positive Rate
TN	True Negative
TNR	True Negative Rate
FP	False Positive
FPR	False Positive Rate
FN	False Negative
FNR	False Negative Rate
PPV	Positive Predictive Value
NPV	Negative Predictive Value