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Demonstrating the Efficacy of a Low-Cost Carbon Dioxide-Based Cryoablation Device in Veterinary Medicine for Translation to Third World Medical Applications

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Abstract : The purpose of this study was to perform a Phase I veterinary clinical trial with a low-cost, carbon-dioxide-based, passive thaw cryoablation device as proof-of-principle for application in pets and translation to third-world treatment of breast cancer. This study was approved by the institutional animal care and use committee. Client-owned dogs with subcutaneous masses, primarily lipomas or mammary cancers, were recruited for the study. Inclusion was based on clinical history, lesion location, preanesthetic blood work, and fine needle aspirate or biopsy confirmation of mass. Informed consent was obtained from the owners for dogs that met inclusion criteria. Ultrasound assessment of mass extent was performed immediately prior to mass cryoablation. Dogs were placed under general anesthesia and sterilely prepared. A stab incision was created to insert a custom 4.19 OD x 55.9 mm length cryoablation probe (Kubanda Cryotherapy) into the mass. Originally designed for treating breast cancer in low resource settings, this device has demonstrated potential in effectively necrosing subcutaneous masses. A dose escalation study of increasing freeze-thaw cycles (5/4/5, 7/5/7, and 10/7/10 min) was performed to assess the size of the iceball/necrotic extent of cryoablation. Each dog was allowed to recover for ~1-2 weeks before surgical removal of the mass. A single mass was treated in seven dogs (2 mammary masses, a sarcoma, 4 lipomas, and 1 adnexal mass) with most masses exceeding 2 cm in any dimension. Mass involution was most evident in the malignant mammary and adnexal mass. Lipomas showed minimal shrinkage prior to surgical removal, but an area of necrosis was evident along the cryoablation probe path. Gross assessment indicated a clear margin of cryoablation along the cryoprobe independent of tumor type. Detailed histopathology is pending, but complete involution of large lipomas appeared to be unlikely with a 10/7/10 protocol. The low-cost, carbon dioxide-based cryotherapy device permits a minimally invasive technique that may be useful for veterinary applications but is also informative of the unlikely resolution of benign adipose breast masses that may be encountered in third world countries.

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