

# Efficacy of Mycobacterial Cell Wall Extract (MCWE) in the treatment of osteosarcoma in dogs

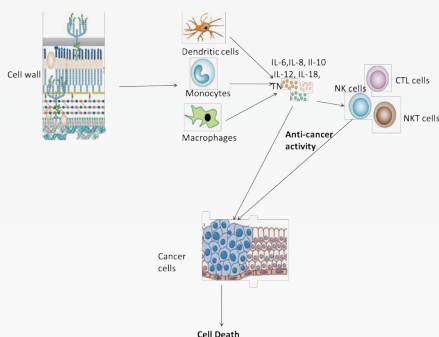
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## INTRODUCTION & OBJECTIVES

Osteosarcoma (OS) is the most common primary bone tumor in dogs, accounting for up to 85% malignancies originating in the skeleton. Amputation of the affected limb is the standard local treatment for canine appendicular osteosarcoma. In general, dogs diagnosed with OS ultimately die of metastatic disease distant to the site of primary tumor, therefore, adequate adjunct therapy to prevent or reduce micro and macro metastasis is highly desirable in OS treatment. Current adjunct therapies in OS treatment include the use of single or multiple chemotherapeutics, while polymer chemotherapy and immunotherapy are still in experimental stages.

Mycobacteria, especially their cell wall, have been known for many years to be active against a variety of tumors. Immunocidin™ is an emulsion of mycobacterial cell wall extract (MCWE) which has been modified to reduce its toxic and allergic effect but retains its immunomodulatory and anti-tumor activity. MCWE stimulates the activation of a variety of cytokines and lymphocytes which, in turn, display potent anti-tumor activity. Here, we demonstrated that administration of MCWE following surgery in dogs diagnosed with OS has a beneficial effect.

Figure 1. MCWE proposed mechanism of action



## MATERIALS & METHODS

Eighteen dogs diagnosed with osteosarcoma were included in the study. Animals were further classified into two groups based on the disease stage at the time of surgery:

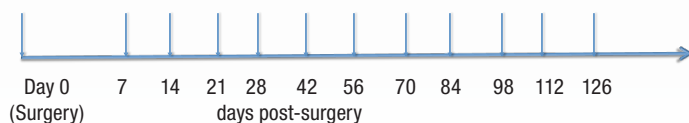
**Group 1.** Animals with localized OS without macroscopic evidence of metastasis (N=12)

**Group 2.** Animals with locally invasive OS and/or regional lymph node involvement (N=6)

None of the animals displayed macroscopic evidence of metastasis in the lungs as determined by x-ray prior to surgery.

MCWE was administered intramuscularly (IM) once a week following surgery for the first month and then every two weeks for the next three months. The first administration occurred on the day of surgery.

Figure 2. Timing of MCWE administration



MCWE dosing was based on the total animal weight:

Dogs < 8 kg (MCWE 90 µg)

Dogs 8 ≤ 15 kg (MCWE 180 µg)

Dogs 16 ≤ 25 kg (MCWE 270 µg)

Dogs 26 ≤ 50 kg (MCWE 360 µg)

## RESULTS

Table 1 . Survival rate for animals in Group 1. localized OS (N=12)

Time (months)	Number of animals survived	% Survival
6	11/12	91.7
9	10/12	83.3
12	9/12	75
18	9/12	75
24	8/12	66.7
36	6/12	50

Table 2. Survival rate for animals in Group 2. locally invasive OS and/or regional lymph node involvement (N=6)

Time (months)	Number of animals survived	% Survival
6	6/6	100
12	3/6	50
24	1/6	16.7

## CONCLUSIONS AND PERSPECTIVES

This pilot study demonstrated that administration of MCWE as an adjunct therapy to appendicular amputation in the treatment of osteosarcoma has the potential to increase the survival rate in canine oncology patients. Additional studies are underway to demonstrate the efficacy of MCWE in combination with different chemotherapeutics or as a standalone therapy in the treatment of various canine cancers.