ORIGINAL RESEARCH

RBAC and Its Role with the Immune System

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ABSTRACT

Context • Rice Bran Arabinoxylan Compound (RBAC) is a trusted and proven immunomodulator made from a rice bran extract that has been enzymatically modified with an enzyme complex from the shiitake mushroom.

Objective • The study's primary objective was to identify the role of RBAC in supporting cancer therapies.

Design • The author designed an open study.

Participants • Participants were 14 patients who are suffering from various type of malignancies.

Intervention • BRM4 capsules—a commercially available, proprietary RBAC supplement—were administered.

Outcome Measures • The study measured circulating tumor cells (CTC) and tumor markers—the prostate-specific antigen (PSA) and cancer antigens 125 (CA125) 15-3 (CA15-3), and 27-29 (CA27-29) for the relevant malignancy.

Results • Twelve out of 14 participants completed the protocol, and two participants died during the study. Of the 12 participants completing the study, the CTC levels were reduced in 10, with a statistically significant difference between the testing at baseline and postintervention ($P = .0047$). The tumor markers of various malignancies decreased for nine out the 12 participants, and one participant experienced remission.

Conclusions • The results suggest that the product can be an effective immunomodulator that can complement conventional cancer treatment.(*Altern Ther Health Med.* 2022;28(1):8-10).

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Conventional cancer treatment, including surgery, chemotherapy, and radiotherapy, may not be sufficient to eradicate all malignant cells and prevent recurrence. Intensive treatment often leads to a depressed immune system, drug resistance, and toxicity, which hampers treatment outcomes.

Rice Bran Arabinoxylan Compound (RBAC) is a serious immunomodulator made from a rice bran extract that has been enzymatically modified with an enzyme complex from the shiitake mushroom. Numerous clinical papers have demonstrated that RBAC modulates the immune system, by increasing the activities of natural killer cells,[1] enhancing macrophage activities,[2] helping mature dendritic cells,[3] and protecting against oxidative stress.[4]

Additionally, clinical studies have also demonstrated that the administration of both chemotherapy and RBAC can increase the survival rate of participants suffering from malignancies compared to a control group not receiving those treatments.[5] In addition, RBAC has been reported to reduce the side effects of chemotherapy, radiotherapy, or radiochemotherapy in participants who were given RBAC during those treatments.[6,7]

It's well known that cancer cells intravasate from the primary site into the blood vessels, circulating in the blood towards distant sites. This phenomena can be seen among people who are suffering from progressive cancers or metastatic cancers. These cancer cells are referred as circulating tumor cells (CTC) and are considered to be a possible marker for diagnosing cancer patients' conditions. In fact, CTC levels have proven to be a significant prognostic factor in metastatic breast cancer.[8]

Although some studies have shown that RBAC can contribute to cancer patients' conditions by enhancing their immune systems and protecting them from oxidative stress, no studies have occurred that show that RBAC has an effect on CTC levels.

The objective of the current study was to identify the role of RBAC in supporting cancer therapies.

METHODS

Participants

The author designed an open study, with 14 patients who are suffering from various type of malignancies. The participants were enrolled in the study after being given a full explanation of its purpose and signing the informed consent.

The types of malignancies included: (1) prostate cancer—all six of the male participants, (2) breast cancer—two female participants, (3) uterine cancer—one female participant, and (4) ovarian cancer—one female participant.

Case 1. This male participant, aged 68, had prostate cancer with local metastasis. He was diagnosed in 2018 and received a course of radiation therapy and total androgen blockade therapy (TAB). His last Lupron injection's effects ended in September 2019.

Case 2. This female participant, aged 56, had been diagnosed with stage 4 ovarian cancer in December 2017. Her CA-125 level was 266 prior to any treatments. A treatment with antineoplastins (burzinski) failed, and multiple chemotherapy treatments also failed.

Case 3. This male participant, aged 70, was first diagnosed with prostate cancer in 2015, and had a Gleason score of 7. The cancer was aggressive. His PSA level when diagnosed was 5.36. He developed hyperthermia and was treated with chemotherapy, with a peak PSA of 130. After treatment with Xtandi, a prescription medicine for advanced prostate cancer, his PSA level was 0.7. He stopped all therapy in 2017.

Case 4. This male participant, aged 69, was diagnosed with prostate cancer in February 2014. He opted for watchful waiting and had a Gleason score of 6. His PSA was 3.4 at diagnosis. He refused any conventional therapies.

Case 5. This female participant, aged 79, had metastatic uterine cancer that had been diagnosed in January 2019. She received radiotherapy to the lymph nodes and a total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAHBSO) surgery in March 2019. Her CA-125 was 55.55 at that time. She refused chemotherapy.

Case 6. This female participant, aged 68, had been diagnosed with ductal carcinoma in situ (DCIS). She underwent surgery but refused chemotherapy.

Case 7. This female participant, aged 78, had metastatic breast cancer and had refused all conventional therapies.

Case 8. This male participant, aged 77, had prostate cancer, with a Gleason score of 6. He refused radiation therapy. His PSA at his initial diagnosis was 6.2.

Case 9. This female participant, aged 67, had intraductal breast cancer and had refused any conventional therapy.

Case 10. This male participant, aged 71, had prostate cancer and had refused any conventional therapy. His PSA was rising at the time the current study began.

Case 11. This male participant, aged 74, had prostate cancer and had refused any conventional therapy. His PSA was rising at the time the current study began.

Case 12: This female participant, aged 78, had stage 4 breast cancer. She had had surgery and had received estrogen blockade, radiotherapy, chemotherapy, and Hoxsey herbal therapy.

Table 1. Circulating Tumor Cells (CTC)

Parameters	Initial Average ± SD	Final Average ± SD	*P* Value (Paired *t* test)
CTCs / 7.5 mL	8.33 ± 8.89	2.33 ± 3.50	.0047

Intervention

Each participant was given six capsules per day for 10 to 19 weeks of a commercially available, proprietary RBAC supplement, BRM4, with 1000 mg/day of RBAC.

Outcome Measures

Tumor markers—the prostate-specific antigen (PSA) and cancer antigens 125 (CA125) 15-3 (CA15-3), and 27-29 (CA27-29)—were measured depending on the type of malignancy. CTCs were measured for all participants.

Statistical Analysis

CTC values were statistically analyzed with the paired *t* test.

RESULTS

The results of the study are shown in Table 1. Twelve participants, 6 males and 6 females aged 56-79, completed the protocol, and two participants died during the study.

Of the 12 participants completing the study, the CTC levels were lowered in 10 between baseline and postintervention, with the difference being statistically significant ($P = .0047$). The other 2 participants showed a CTC value of 0 both at baseline and postintervention.

Participants' tumor markers—PSA, CA125, CA15-3, and CA27-29—decreased in 9 participants, and one participant experienced remission.

Case 1. The participant's RBAC protocol was initiated in October 2019. The dose of RBAC was the only new thing added to his regimen. Postintervention, in January 2020, his CTC was zero as compared to 7 at baseline. His PSA level postintervention was <0.018, and prior to the RBAC, it had never been stable after he stopped receiving Lupron.

Case 2. The participant's RBAC protocol was initiated in October 2019. Postintervention in January 2020, her CTC was 2 as compared to 13 at baseline. Her CA-125 was 6.3 postintervention as compared to 266 in December 2017.

Case 3. The participant's RBAC protocol was initiated in October 2019. Postintervention, in January 2020, his CTC was 4 and his PSA was 0.7 as compared to 15 and 34.24, respectively, at baseline.

Case 4. The participant's RBAC protocol was initiated in November 2019. Postintervention, in January 2020, his CTC was zero, and in February 2020, his PSA was 10.49 as compared to 0 and 8.72, respectively, at baseline.

Case 5. The participant's RBAC protocol was initiated in October 2019. Postintervention in February 2020, her CTC was 12 and her CA 125 was 11.74 as compared to 32 and 36.16, respectively, in November 2019. Her PET/CT scan was

clean on February 28, 2020. She was declared in remission by her oncology team.

Case 6. The participant's RBAC protocol was started in November 2019. Postintervention in February 2020, her CTC was 0 and her CA15-3 was 42 as compared to 2 and 42, respectively, at baseline. Her tumor markers were always negative.

Case 7. The participant's RBAC protocol started in December 2019. Postintervention in March 2020, her CTC was 0 as compared to 4 at baseline. Her tumor makers were always negative.

Case 8. The participant's RBAC protocol was initiated in September 2019. Postintervention in January 2020, his PSA was 5.14 and his CTC was zero as compared to 7.8 and 7, respectively, at baseline.

Case 9. The participant's RBAC therapy was initiated in October 2019. Postintervention in January 2020, her CTC was 4 and her CA15-3 was 33 as compared to 11 and 56, respectively, at baseline. Her CT scans in September 2019 showed stage 5 hypermetabolic reading in the left breast, and in February 2020, the scans showed a stage 2 hypermetabolic reading and a stable size.

Case 10. The participant's RBAC protocol was initiated in October 2019. Postintervention in February 2020, his PSA was 6.7 and his CTC was 2 as compared to 15.3 and 3, respectively, at baseline.

Case 11. The participant's RBAC protocol was initiated in October 2019. Postintervention in February 2020, his PSA was 6.91 and his CTC was 4 as compared to 14.32 and 6, respectively, at baseline.

Case 12. The participant's RBAC protocol was initiated in October 2019. Postintervention in February 2020, her CA15-3 was 357, her CA 27-29 was 462, and her CTC was negative as compared to 1247, 1543, and negative, respectively, at baseline.

DISCUSSION

CTC have proven to be a significant prognostic factor in metastatic breast cancer. The current study demonstrated that CTCs had been reduced for 2 breast-cancer patients. In addition, CTCs had been lowered for 10 out of 12 participants. The CTC levels were significantly reduced for 10 out of 12 participants as compared to baseline ($P = .0047$). In addition, tumor markers—PSA, CA125, CA15-3, andCA27-29 were decreased for 9 participants out of 12.

For cancers other than breast cancer, the relationship between CTC levels and medical condition isn't always clear. However, administration of RBAC improved the symptoms of almost all participants, taking into the consideration the fact that their tumor makers were lowered.

CONCLUSIONS

This current study has shown that administration of RBAC can lower the CTC levels of cancer patients, which suggests that RBAC can be a potent immunomodulator and an adjuvant to cancer treatment. The current study was a relatively small scale study, and further studies are encouraged.

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