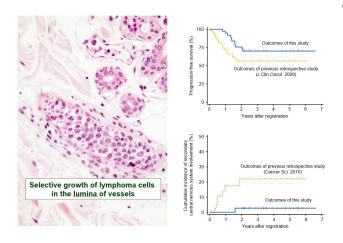


Clinical trial shows promising new treatment for rare blood cancer

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Novel therapy in intravascular large B-cell lymphoma. Credit: Kazuyuki Shimada

Lymphoma is a type of blood cancer that develops from lymphocytes (a type of white blood cell). It has many subtypes. A rare subtype, called intravascular large B-cell lymphoma (or IVLBCL) is notably hard to diagnose accurately because the cancerous lymphocytes grow inside small blood vessels, instead of at lymph nodes, and there is no perceptible swelling/enlargement of lymph nodes. There is also no effective treatment: the disease tends to affect the elderly, for whom standard highdose chemotherapy may have serious side-effects, and patients are at a high risk of developing subsequent central nervous system (CNS) disorders even with treatment. A novel treatment protocol with fewer side-effects and which also tackles secondary CNS involvement is needed, and this is exactly what a group of scientists, led by researchers from Nagoya University and Mie University, Japan, attempted to test in a new clinical trial.

However, the rarity of this disease has made testing new combinations of drugs difficult. A previous "retrospective" study involving the

analysis of medical records of patients who had undergone standard chemotherapy combined with a drug called "rituximab" showed that this line of treatment is more promising than standard treatment alone, but it does not solve the problem of secondary CNS involvement. "We considered that rituximab-containing chemotherapies combined with treatment for the secondary CNS problems could lead to further improvement in the clinical outcome," remarks Dr. Kazuyuki Shimada of Nagoya University. With this consideration, Dr. Shimada and team conducted a Phase 2 multicenter clinical trial, where they administered their proposed treatment to 38 enrolled patients (aged 20 to 79 years and without CNS disorders at the time of cancer diagnosis) and monitored their conditions over the long term. The results are published in their paper in The Lancet Oncology.

Overall, their treatment protocol appears to be promising: 76% of the enrolled patients reached the primary goal of two-year survival without disease progression and 92% reached two-year overall survival. The disease affected the CNS in only 3% of patients. What's more, the toxicity of the treatment was found to be low, and all adverse effects were manageable, with very few serious complications.

Aptly summarizing their achievement, Dr. Shimada says: "To the best of our knowledge, this is the first 'prospective' trial of any treatment in patients with IVLBCL. It appears that the proposed treatment protocol might be effective in patients without apparent central nervous system involvement at the time of diagnosis."

An important advantage of the proposed treatment protocol is that it employs a combination of conventional drugs and uses no novel agents. This means that although further study is necessary, this protocol can be adopted in clinical practice in the very near future. As Dr. Shimada explains: "Given the rarity of this disease, a large-scale Phase 3

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prospective trial is not feasible. In such a scenario, the results of our trial provide a safe and <u>effective</u> <u>treatment</u> option that can function as a historic control for future prospective <u>trials</u>."

The findings of this clinical trial are certainly quite promising. With only minor refinements to the proposed treatment <u>protocol</u>, patients with IVLBCL could have an edge in their fight against cancer.

This study, "Rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone combined with high-dose methotrexate plus intrathecal chemotherapy for newly diagnosed intravascular large B-cell lymphoma (PRIMEUR-IVL): a multicentre, single-arm, phase 2 trial," has been published in *The Lancet Oncology*.

More information: Kazuyuki Shimada et al. Rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone combined with high-dose methotrexate plus intrathecal chemotherapy for newly diagnosed intravascular large B-cell lymphoma (PRIMEUR-IVL): a multicentre, single-arm, phase 2 trial, *The Lancet Oncology* (2020). DOI: 10.1016/S1470-2045(20)30059-0

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