Cancer Association of South Africa (CANSA)

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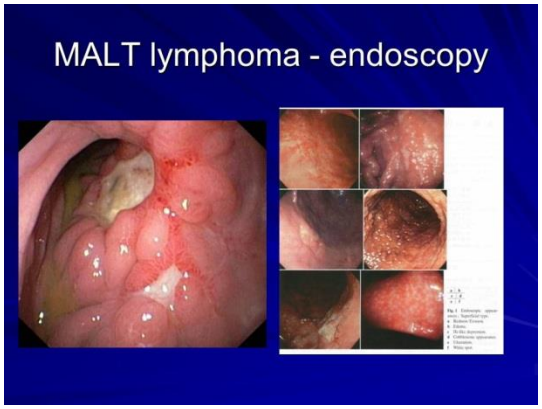
Fact Sheet on Mucosa Associated Lymphoid Tissue (MALT) Lymphoma

Introduction

Like all lymphomas, Mucosa Associated Lymphoid Tissue (MALT) Lymphoma, is a cancer of the lymphatic system which is part of the body's immune system. It develops when white blood cells, called B-lymphocytes, become abnormal and begin to grow in an uncontrolled manner. It is frequently of the stomach, but virtually any mucosal site can be afflicted. It is a cancer originating from B cells in the marginal zone of the MALT, and is also called extranodal marginal zone B cell lymphoma. (MacMillan Cancer Support; Wikipedia).



[Picture Credit: MALT Lymphoma]

MALT Lymphoma

MALT lymphoma or Marginal Zone Lymphomas are B-cell lymphomas. They are not very common and account for a small percentage of non-Hodgkin's lymphomas (NHLs). There are 3 main types of marginal zone lymphomas:

- extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma)
  - MALT lymphomas may also be called maltomas.
  - This is the most common type of all the marginal zone lymphomas.
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

Extranodal marginal zone lymphomas start in tissues or organs outside of the lymph nodes (extranodal). MALT lymphoma develops in mucosa-associated lymphoid tissue, in the mucosa or tissue that lines body organs or body cavities including:

- gastrointestinal (GI) tract
  - The stomach is the most common location for MALT lymphoma, but it can also occur in the small bowel and colon

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- lungs
- eyes, including the orbit (bony cavity that the eyeball sits in)
- skin
- salivary glands
- thyroid gland
- breasts

MALT lymphomas are the third most common type of NHL and account for about 8% of all cases of NHL. Most MALT lymphomas occur in people in their 60s.

Many people are diagnosed with localised or early stage disease that has not spread elsewhere in the body. MALT lymphomas are usually slow growing (indolent), but some can be high grade. They often remain in the area in which they started for a long period of time. Rarely, MALT lymphomas can change (transform) into a more aggressive large cell lymphoma.
(Canadian Cancer Society).

Incidence of MALT Lymphoma in South Africa
The National Cancer Registry (2012) does not provide any information regarding the incidence of MALT Lymphoma.

According to the National Cancer Registry of 2012, the following number of Non-Hodgkin's Lymphoma cases was histologically diagnosed in South Africa during 2012:

Group - Males 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	933	1:206	2,53%
Asian males	29	1:222	3,39%
Black males	555	1:274	4,76%
Coloured males	79	1:212	1,81%
White males	271	1:121	1,35%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	797	1:311	2,12%
Asian females	21	1:333	1,96%
Black females	500	1:401	3,03%
Coloured females	70	1:272	1,68%
White females	206	1:179	1,30%

The frequency of histologically diagnosed cases of Non-Hodgkin's Lymphoma in South Africa for 2012 was as follows (National Cancer Registry, 2012):

Group - Males 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	32	46	134	208	199	146	105	49
Asian males	1	0	2	4	7	5	5	2
Black males	24	33	108	158	127	53	22	9
Coloured males	3	5	9	12	18	12	11	6
White males	4	8	12	30	44	74	62	31

Group - Females 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	17	50	144	188	141	106	92	44
Asian females	0	0	2	4	6	3	4	0
Black females	11	39	120	156	81	37	27	10
Coloured females	2	3	8	14	9	13	14	6
White females	4	8	13	12	43	49	47	26

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

Signs and Symptoms of MALT Lymphoma
Symptoms depend on where the MALT lymphoma starts.

The most common symptoms of MALT lymphoma that starts in the stomach is indigestion or heartburn. Some people also have weight loss, feeling or being sick and stomach (abdominal) pain.

In most people gastric MALT lymphoma is found during tests for persistent indigestion – although only a very small percentage of people with indigestion or heartburn will have lymphoma. The indigestion is probably more related to the presence of the *H. pylori* infection than to the lymphoma and people often feel better after they have had treatment to eradicate the infection, whether or not the lymphoma is regressing (decreasing).

A few people with gastric MALT lymphoma go to their doctor with other symptoms, such as abdominal pain, nausea (feeling sick), vomiting (possibly with specks of blood in the vomit) and weight loss. Some people will have symptoms of anaemia, such as tiredness and shortness of breath, because the stomach lining has been bleeding, but this is quite rare. Severe abdominal pain or the finding of a lump or mass in the abdomen would also be unusual.
(Cancer Research UK; Lymphoma Association).

Diagnosis of MALT Lymphoma
For a gastric MALT lymphoma to be diagnosed, the stomach lining has to be examined and biopsied. Tests for *H. pylori* infection are also needed to confirm the diagnosis.

Endoscopy - MALT lymphoma is usually discovered unexpectedly during an endoscopy examination of the stomach. This is a test in which a flexible tube with a light and a tiny camera in its tip is passed down through the mouth into the stomach. One would normally be offered a sedative when having this test. The lining of the stomach might just look generally inflamed or swollen. It is quite common to see ulcers. In a few people a nodular (lumpy) mass might be seen in the stomach during endoscopy.

Biopsy - It is very difficult, and often impossible, to tell the difference between lymphoma and the much more common kind of stomach cancer just by looking at these ulcers or nodules during the endoscopy examination, so small samples of the stomach lining – biopsies – will be taken during the endoscopy. The biopsies will be examined under the microscope, when the pathologist will assess:

- the size and shape of the lymphoid cells
- where the cells are positioned within the stomach lining
- how the cells interact with the other parts of the stomach wall. Sometimes, reaching a diagnosis can even be difficult when the samples are examined under the microscope.

Biopsies are, therefore, often put through more detailed tests, sometimes in another laboratory, and this can take up to 2–3 weeks. These tests are done to look at the types of proteins on the surface of the lymphoma cell (immunohistochemistry tests) and at the genetic make-up of the lymphoma cells (cytogenetics tests). These specialised tests help the doctors to predict how well the lymphoma is likely to respond to therapy.

Sometimes, even using the latest sensitive techniques, it may not be possible to distinguish confidently between a lymphoma and inflammation in the stomach and several biopsies and more than one endoscopy are needed.

Testing for *H. pylori* organisms - It is very important that the presence of the *H. pylori* organism is confirmed so that a firm diagnosis can be made. This has often already been tested for before the endoscopy. There are several ways of testing for this. In one method a stool sample is collected and tested. Sometimes the organisms are very scanty and difficult to find and one might have other tests done to look for evidence of the infection.
(Lymphoma Foundation).

Staging of MALT Lymphoma
The Ann Arbor Staging System is the most commonly used staging system for patients with NHL.

- Stage I: involves a single lymph node region (I) or localised involvement of a single extralymphatic organ or site (IE).

- Stage II: two or more lymph node regions on the same side of the diaphragm (II) or localised involvement of a single associated extralymphatic organ in addition to criteria for stage II (IIE).

- Stage III: lymph node regions on both sides of the diaphragm (III) that also may be accompanied by localised involvement of an extralymphatic organ or site (IIIE), spleen (IIIS), or both (IIISE).

- Stage IV: disseminated or multifocal involvement of one or more extralymphatic sites with or without associated lymph node involvement or isolated extralymphatic organ involvement with distant node involvement.

Subscript letters represent involvement of extralymphatic organs: L - lung, H - liver, P - pleura, O - bone, M - bone marrow, D - skin. E is used when extranodal lymphoid malignancies arise in tissues that are separate from, but near to, the major lymphatic aggregates.

Stages I-IV can be followed by A or B designations:
- A - no systemic symptoms.

- B - any of the following symptoms: unexplained loss of more than 10% of bodyweight in the preceding six months before diagnosis, unexplained fever with temperature above 38°C, and drenching night sweats.

(Chronic Illness Support).

Treatment of MALT Lymphoma

The initial treatment for gastric MALT lymphoma is a course of treatment to eradicate the *H. pylori* infection. This will successfully treat the lymphoma in most people who showed evidence of *H. pylori* infection in their tests.

Some people will need to have this eradication treatment more than once and a few people will go on to need other treatments such as chemotherapy or radiotherapy. *H. pylori* eradication Treatment of the H. pylori infection leads to regression of the lymphoma in about 8 out of every 10 people with gastric MALT lymphoma who showed evidence of an H. pylori infection.

The treatment is most successful when the tumour has not extended very far through the stomach wall and has not spread to the lymph nodes. One would normally be prescribed an initial course of antibiotic treatment for *H. pylori* eradication – clarithromycin together with either amoxicillin or metronidazole. These antibiotics are usually given with a drug that cuts down the amount of acid the stomach produces (a proton pump inhibitor or 'PPI' drug such as omeprazole). This combination of three drugs is often called ‘triple therapy’ and is taken for 10–14 days.

A few weeks after the eradication treatment has finished the patient will be tested again for *H. pylori* infection. This is sometimes done using a simple 'breath test', in which a sample of breath is analysed after the patient has had a special drink. If tests show that the infection is still there, the patient will be given another course of antibiotics, usually using different drugs from those used in the first course. Then the patient would be tested for the infection again. The interval of time between eradication of the *H. pylori* infection and regression (disappearance) of the lymphoma is very variable.

In some people the lymphoma might be found to have regressed at the first follow-up biopsy. In other people it can take a year or more for the lymphoma to go away completely. If the *H. pylori* treatment is successful the patient will not need any other treatment.

(Lymphoma Foundation).

Follow-up Upon Completion of Treatment

After the course of eradication therapy the patient will have a test (usually a breath test) to check for *H. pylori* about 4–6 weeks after the treatment has finished. About 3–6 months after the treatment has finished the patient will usually have another endoscopy.

A biopsy is usually also taken during this endoscopy to make sure that the infection has been eradicated and to assess whether the lymphoma is decreasing. After that the patient might expect to have endoscopy examinations about every 4–6 months at first, dropping eventually to once a year. Biopsies might be taken at these later endoscopies if the medical team feel this would be helpful. The timing of the follow-up visits and examinations will depend on many factors, such as how long it has taken for the lymphoma to regress completely and what treatments the patient has had.

The outlook for people with gastric MALT lymphoma is good, so some clinics discharge patients after a fixed time of being in remission (when there is no sign of the lymphoma). Other doctors follow up their patients with gastric MALT indefinitely. The treating team will provide the patient with information on what to expect.

In a small proportion of people a follow-up endoscopy will show that the lymphoma has relapsed (come back). If the *H. pylori* infection has also come back, this usually responds to further antibiotic-based therapy. In a small number of people, relapse detected on microscopic examination of a biopsy clears spontaneously with no further treatment at all, so it is quite common to monitor this situation without giving further treatment.

A few patients whose lymphoma has clearly come back will be treated with chemotherapy and/or radiotherapy in the same way as people who do not respond to the initial eradication therapy are treated. These are very effective treatments in these circumstances too.

In around 1 in 10 people the lymphoma turns into a faster-growing form of lymphoma called 'diffuse large B-cell lymphoma'. This is called 'transformation'. When this happens the lymphoma is usually treated with intravenous chemotherapy using a combination of drugs, with the aim of curing this more aggressive disease.

About Clinical Trials

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

Types of Clinical Trials

Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

Prevention - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer

Screening - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that

type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

Diagnostic - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

Quality of life or supportive care - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as "human subjects."

Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different “phase” in the clinical research process. The following phases are used for cancer treatment trials:

Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the

safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or "trial arms": (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

Use of Placebos

The use of placebos as comparison or “control” interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as ‘biospecimens’) obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.
(National Cancer Institute).

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