Medivizor Picks 2013's Top 10 Papers: Breast Cancer

About this eBook

Medivizor's medical experts have chosen 10 of the most important research papers of 2013 for breast cancer patients and compiled them into this short eBook.

Medivizor subscribers received these, and other interpreted summaries, based on the articles' relevance to their specific diagnoses and health situation.

There are many other important research publications that were not included in this list. Exclusion from this eBook does not diminish the scientific importance of an article. In fact, Medivizor believes the article's importance to doctors and patients depends highly on their personal situation.

About Medivizor

Medivizor is a new and unique health information and patient education service.

Whenever people become seriously or chronically sick, they or someone that cares for them, often become "chronic web researchers." The process of finding relevant, trustworthy and understandable information across the entire web is extremely ineffective and inefficient.

Medivizor's mission is to improve the lives of people with serious medical conditions and those who care for them by providing truly relevant information that can help. The Medivizor solution, that combines patent-pending technology, medical expertise, and the wisdom of the crowd, is now live in public beta. The service currently supports over 400 medical conditions in 10 domains, including 88% of cancer incidence (prostate cancer, breast cancer, colorectal cancer, lung cancer, and melanoma), diabetes (including type-1, type-2, pre-diabetes, and gestational diabetes), 75% of cardiovascular disease (stroke, heart attack, hypertension), and infertility. This list of supported conditions continues to expand. Check medivizor.com for the most updated list.

The summaries in this eBook are examples of the content that Medivizor subscribers receive. The summaries are based on the best and most credible research and are designed for patients and caregivers who possess 10th grade level English reading skills. Similarly, subscribers receive information related to cutting-edge research, treatment options, matching clinical trials, updated guidelines, lifestyle tips, and more.

Articles Reviewed

1	Can magnetic resonance imaging correctly diagnose remaining breast cancer after chemotherapy before surgery?	http://bit.ly/1hQ1kMU
2	Trastuzumab emtansine as treatment for advanced HER2 positive breast cancer	http://bit.ly/OID4np
3	Circulating tumor DNA as a new biomarker	http://bit.ly/1evB4sj
4	Preventing fever during chemotherapy	http://bit.ly/1gQZOw0
5	Does removal of the primary tumor improve survival in stage IV breast cancer?	http://bit.ly/1gjKJ7y
6	Evaluating treatment options to preserve fertility in young breast cancer patients treated with chemotherapy	http://bit.ly/1hQ4DUu
7	Keeping score on the risk of recurrence	http://bit.ly/1fN36vG
8	Could intraoperative radiotherapy replace standard irradiation treatments?	http://bit.ly/1gQznXq
9	What can predict cancer recurrence in node-negative patients	http://bit.ly/1jd9nZx
10	Everolimus effective and safe in addition to exemestane among elderly women	http://bit.ly/1iLN1vC

Can magnetic resonance imaging correctly diagnose remaining breast cancer after chemotherapy before surgery?

In a nutshell

This review evaluated several studies comparing magnetic resonance imaging (MRI) to mammography, ultrasound and clinical examination after neoadjuvant chemotherapy in breast cancer patients. The aim was to see if MRI more accurately identified patients who had responded well to chemotherapy and obtained a pathologic complete response.

Some background

Chemotherapy before surgery in breast cancer patients is known as neoadjuvant chemotherapy (NAC). The aim of NAC is to shrink the cancer in the breast tissue and destroy cancer cells that have spread beyond the breast. This is called a pathologic complete response. Following NAC, if the cancer is still invading nearby breast tissue or lymph nodes, it is called residual cancer. Shrinking the cancer before surgery increases the chances that the cancer will be completely removed during surgery. MRI is a test that uses magnetic and radio waves to make pictures of tissues, organs and other structures of the body. These pictures can be viewed and stored on a computer. This makes it useful to identify cancer in the breast or that has spread to the surrounding lymph nodes or to other tissues and organs. Mammography uses x-rays to locate and diagnose breast cancers and ultrasound uses sound waves to make pictures of tissues and organs of the body. The authors of this study compared MRI to mammography and ultrasound in correctly identifying residual cancer in patients undergoing NAC for breast cancer.

Methods & findings

This article looked at the results of 44 clinical studies which included overall 2050 patients newly diagnosed with breast cancer. All patients were treated with NAC and under-went MRI afterwards, to see if there was any residual cancer before surgery. Some patients also underwent mammography, ultrasound or clinical examination of the affected breast as alternative diagnositic method to MRI. Results show that MRI correctly detected residual breast cancer. Moreover, MRI was significantly more accurate in detecting residual invasive breast cancer after NAC than mammography, but not when compared to cheaper techniques such as ultrasound and clinical examination.

The bottom line

Overall this study showed that MRI was very useful in detecting residual cancer after NAC in patients with breast cancer.

The fine print

A drawback for this research was that definitions for a pathologic complete response varied between the studies included. Also, there were fewer studies comparing MRI to ultrasound than those comparing MRI to mammography. Therefore, to accurately determine whether MRI has more benefits than ultrasound examination in detecting residual breast cancer, more quality clinical trials are required.

Published Online By: Journal of the National Cancer Institute (JNCI)

Date: Jan 7, 2013

Original Title: Meta-analysis of magnetic resonance imaging in detecting residual breast cancer after neoadjuvant therapy

Marinovich, M., et.al.,(2013) Meta-analysis of magnetic resonance imaging in detecting residual breast cancer after neoadjuvant therapy. JNCI J Natl Cancer Inst 105(5): 321-333.doi: 10.1093/jnci/djs528

Trastuzumab emtansine as treatment for advanced HER2 positive breast cancer

In a nutshell

This trial compared treatment with trastuzumab (herceptin) in combination with docetaxel, to a new combination drug called trastuzumab emtansine.

Some background

Some breast cancer cells have certain receptors on their surface that respond to growth inducing molecules. These cancers are referred to as being human epidermal growth factor receptor type 2 positive (HER2+). HER2+ cancers are known to respond to a drug called trastuzumab (herceptin), which targets and blocks the action of these receptors. Trastuzumab is often used in combination with chemotherapy, especially in the case of advanced cancers. Docetaxel is an example of a commonly used chemotherapeutic drug. Nowadays, a new form of trastuzumab is being developed. Trastuzumab emtansine (T-DM1), combines trastuzumab, and directly tied to it a chemotherapy drug called mertansine. When trastuzumab attaches to its target on breast cancer cells, the chemotherapeutic drug is delivered directly into the cancer cells. This could potentially reduce many of the side effects associated with chemotherapy and improve patient outcome.

Methods & findings

137 women with advanced HER2+ breast cancer were treated with either T-DM1 or with trastuzumab and docetaxel
Results showed that patients treated with T-DM1 had a longer period of time before their cancer progressed. Additionally, T-DM1 was shown to be safer, with only 46.4% of patients suffering severe adverse events. This compared to 90.4% of patients in the trastuzumab and docetaxel treatment group.

The bottom line

Overall this study shows trastuzumab emtansine (T-DM1) to be a safe and effective treatment option for HER2 positive breast cancer.

The fine print

This trial is an early phase study (phase II), involving only a small group of patients. Additional research is still needed on this new treatment option.

Published By: Journal of Clinical Oncology
Date: Feb 4, 2013
Original Title: Phase II Randomized Study of Trastuzumab Emtansine Versus Trastuzumab Plus Docetaxel in Patients With Human Epidermal Growth Factor Receptor 2–Positive Metastatic Breast Cancer

Hurvitz, S. et.al., (2013). Phase II randomized study of Trastuzumab Emtansine versus Trastuzumab plus Docetaxel in patients with human epidermal growth factor receptor 2-positive metastatic breast cancer. JCO . 31 (9): 1157-1163. doi:10.1200/JCO.2012.44.9694.

Circulating tumor DNA as a new biomarker

In a nutshell

This trial investigated the significance of circulating tumor DNA as a biomarker for monitoring response to treatment among metastatic breast cancer patients.

Some background

The management of metastatic breast cancer requires frequent monitoring of response to treatment in order to avoid ineffective therapies and prevent unnecessary side effects. Normally, cancer response to therapy is monitored by imaging tests or the levels of certain biomarkers (molecules detected by blood test, whose levels indicate the extent of the cancer within the body). However, both radiographic imaging and the commonly used breast cancer biomarker cancer antigen 15-3 (CA 15-3) have demonstrated limited accuracy in previous studies. Circulating tumor DNA (fragments of the tumor's genetic material) is currently being investigated as a possible new biomarker used to assess tumor extent (often referred to as tumor burden) and response to treatment.

Methods & findings

30 women with metastatic breast cancer and undergoing treatment were included in this study. Circulating tumor DNA, as well as CA 15-3 levels and the number of circulating tumor cells (another commonly used biomarker) were assessed and followed throughout treatment. Circulating tumor DNA showed the greatest sensitivity to tumor burden. Circulating tumor DNA was successfully detected in 97% of women, compared to CA 15-3 which was detected in 78% of women, and circulating tumor cells which were detected in 87% of women.

Circulating tumor DNA levels also showed a greater correlation with changes in tumor burden throughout treatment compared to CA 15-3 or circulating tumor cells. Among women with a progressing disease despite treatment, circulating tumor DNA levels increased in 89% of women, compared to 37% of women showing an increase in circulating tumor cells and 50% showing an increase in CA 15-3 levels. In addition, increasing levels of circulating tumor DNA were also found to be associated with inferior overall survival.

The bottom line

This study concluded that circulating tumor DNA can provide an accurate assessment of tumor burden and response to treatment among metastatic breast cancer patients.

The fine print

This study included only a very small number of participants. Larger studies examining the prognostic significance of circulating tumor DNA are awaited.

Published By: The New England Journal of Medicine

Date: Mar 28, 2013

Original Title: Analysis of circulating tumor DNA to monitor metastatic breast cancer

Dawson, SJ. (2013). Analysis of circulating tumor DNA to monitor metastatic breast cancer. N Engl J Med. 368:1199-1209. DOI: 10.1056/NEJMoa1213261.

Preventing fever during chemotherapy

In a nutshell

This study examined the timing and effectiveness of G-CSF treatments during chemotherapy in breast cancer patients at risk for febrile neutropenia.

Some background

A common side effect of chemotherapy is neutropenia, a reduction in the number of neutrophils (the most common type of white blood cells). Neutrophils are a crucial part of the body's immune system without which the body is unable to fight infections. Febrile neutropenia (FN) is defined as a fever (indicating an infection) that occurs in a patient with neutropenia. FN can lead to prolonged hospitalization, delay of chemotherapy and may be life threatening.
Granulocyte colony-stimulating factor (G-CSF) is a protein that stimulates the production of new white blood cells. Treatment with G-CSF is recommended for patients at an increased risk of developing FN, such as patients receiving certain chemotherapy regimens. However, G-CSF treatments are very expensive. Since the risk of FN is known to be highest during the first two cycles of chemotherapy, this study investigated whether G-CSF could be safely limited only to the first cycles of treatment.

Methods & findings

167 patients beginning chemotherapy treatments and at an increased risk of developing FN were included in the study.

Patients were randomly assigned to receive G-CSF either only during the first two chemotherapy cycles, or throughout all treatment cycles.

10% of patients who received G-CSF throughout all chemotherapy cycles developed FN. In comparison, 36% of patients who received G-CSF only during the first two treatment cycles developed FN. Among patients receiving G-CSF only during the first two treatment cycles, the incidence of FN was highest (24%) during the third chemotherapy cycle (the first without G-CSF).

The bottom line

This trial concluded that G-CSF treatments should be continued throughout all chemotherapy cycles. Limiting G-CSF treatment to the first two cycles of chemotherapy significantly increases the risk of febrile neutropenia.

The fine print

Only a small number of patients were included in this study.

Published By: Journal of Clinical Oncology
Date: Apr 29, 2013
Original Title: Primary Granulocyte Colony-Stimulating Factor Prophylaxis During the First Two Cycles Only or Throughout All Chemotherapy Cycles in Patients With Breast Cancer at Risk for Febrile Neutropenia

Aarts, MJ. et.al. (2013) Primary granulocyte colony-stimulating factor prophylaxis during the first two cycles only or throughout all chemotherapy cycles in patient s with breast cancer at risk for febrile neutropenia. Journal of Clinical Oncology. 31(34):4290-6. doi: 10.1200/JCO.2012.44.6229.

Does removal of the primary tumor improve survival in stage IV breast cancer?

In a nutshell

This analysis of several case studies evaluated whether removal of primary tumor in stage IV breast cancer helps improve overall survival.

Some background

In stage IV (metastatic) breast cancer, the cancer spreads beyond the breast and nearby lymph nodes, to other organs and tissues of the body, such as the lungs, liver, bones or brain. Treatments for stage IV breast cancer usually aim at lowering the extent of metastases (spreading of cancer cells to distant organs), extending survival and improving patients' quality of life. The general belief is that in stage IV breast cancer, survival depends on the extent of metastases and that the local removal of the primary cancer does not improve the survival rate. At the same time, surgical removal of the primary tumor has shown to improve survival in other types of cancer, such as skin, kidney or bowel cancer. The present study aimed to determine whether removal of the primary cancer has any effect on survival in breast cancer patients.

Methods & findings

For this research, the authors analyzed several studies that evaluated survival rates in stage IV breast cancer patients after removal of the primary tumor. Overall, data from ten studies were included, where 28693 patients with stage IV breast cancer participated. Of these, 15162 patients underwent surgery to remove the primary cancer, while 13531 received systemic (whole body) treatment only, such as chemotherapy or hormonal therapy. Of the patients treated with surgery, 61% underwent a mastectomy (removal of the whole cancer-affected breast) and 39% underwent breast conserving surgery or a lumpectomy (removal of the cancerous lump only). Results showed that the survival rate 3 years after the treatment was 40% in the surgery-treated group compared to 22% in patients who did not undergo surgery. However, patients treated with surgery tended to have smaller tumors and fewer metastases compared to patients who did not have surgery.

The bottom line

In summary, stage IV breast cancer patients who underwent surgical removal of the primary tumor had significantly higher survival rates compared to patients treated with systemic therapies only. However, this was applicable to only a select group of patients, with relatively good health status before the operation.

The fine print

A drawback for this study stems from the fact that it analyses studies that have been done in the past (retrospective studies), rather than following patients throughout their treatment and determining their outcomes (prospective studies). Future prospective studies are needed in order to determine the actual effects on survival of surgical removal of the primary tumor in stage IV breast cancer patients.

Published By: Annals of Surgical Oncology
Date: May 22, 2013
Original Title: Meta-Analysis to Determine if Surgical Resection of the Primary Tumour in the Setting of Stage IV Breast Cancer Impacts on Survival

Harris, E., Barry, M., Kell, M. (2013). Meta-analysis to determine if surgical resection of the primary tumour in the setting of stage iv breast cancer impacts survival. Annals of Surgical Oncology. 20 (9): 2828-2834. doi: 10.1245/s10434-013-2998-2

Evaluating treatment options to preserve fertility in young breast cancer patients treated with chemotherapy

In a nutshell

This study evaluated whether taking a hormone called gonadotropin releasing hormone analog (GnRHa) during chemotherapy helps breast cancer patients preserve their fertility and prevent premature ovarian failure (POF).

Some background

In breast cancer, cells are dividing more rapidly than normal cells. Chemotherapy or medicines that kill cancer cells often target other rapidly dividing cells in the body. The ovaries (female reproductive organs where egg cells are made) normally have rapidly dividing cells, which means the chemotherapy drugs can also target the ovaries. When this happens in young, premenopausal (before menopause) women, they can lose normal function of the ovaries. This means that their ovaries will stop producing mature eggs and the hormone estrogen. This is called premature ovarian failure (POF). A common result of POF is infertility (inability to conceive). One current method of avoiding POF is to get the ovaries to stop making mature egg (a process called ovulation) cells during chemotherapy. GnRHa is a type of therapy used to stop the ovaries to produce estrogen, which will in turn stop ovulation. This process is thought to make the ovaries less targeted by the chemotherapy. When the GnRHa therapy is stopped, patients who still have functioning ovaries should start having periods again on their own. This is called spontaneous resumption of menses.

Methods & findings

This study combined the results of 7 different previous studies from 2000-2012 which included a total of 677 premenopausal women diagnosed with breast cancer. All patients were treated with chemotherapy for breast cancer. The study compared results for patients who received GnRHa together with chemotherapy and for those who did not. Results show that patients who received GnRHa therapy together with chemotherapy had a 2.83 times higher chance of resuming their menses compared to patients who did not receive GnRHa therapy.

The bottom line

In conclusion, this study showed that young women with breast cancer who received GnRHa therapy together with chemotherapy had an increased chance to have spontaneous menses compared to patients who did not receive GnRHa therapy. These results show a potential benefit of GnRHa therapy in preserving fertility in premenopausal breast cancer patients treated with chemotherapy.

The fine print

Most studies included were small and large study data is lacking in this area. There was no information on GnRHa side effects, or egg reserve (number of good eggs left after chemotherapy).

Published By: PLOS ONE
Date: Jun 21, 2013
Original Title: Gonadotropin-Releasing Hormone Analog Cotreatment for the Preservation of Ovarian Function during Gonadotoxic Chemotherapy for Breast Cancer: A Meta-Analysis

Wang, C. et.al. (2013).Gonadotrophin-releasing hormone analog cotreatment for the preservation of ovarian function during gonadotoxic chemotherapy for breast cancer: A meta-analysis. PLOS One: 2013 Jun 21;8(6):e66360

Keeping score on the risk of recurrence

In a nutshell

This study investigated different scoring scales that could be used to determine the risk of recurrence among estrogen receptor-positive (ER+) breast cancer survivors.

Some background

Breast cancer survivors are at risk of developing distant recurrence of the cancer even many years after initial treatments. Since usually treatments aimed at reducing the risk of recurrence are continued for 5 years following initial diagnosis, it is important to determine which women are at an increased risk of late recurrence. Cancer characteristics, such as the genetic profile of the tumor, different molecular signatures or size and lymph node involvement, may all be used to predict the likelihood of late recurrence and identify patients that may benefit from extended treatment.

Several scoring scales are commonly used to predict the risk of breast cancer recurrence. The immuno-histochemical score (IHC4) is based on the presence or absence of four molecular markers such as estrogen and progesterone receptors. The clinical treatment score (CTS) contains information regarding lymph node involvement, tumor size and patient age. Two scoring systems are used that determine the genetic profile of the cancer. The recurrence score (RS) is provided by the Oncotype DX test, and the risk of recurrence score (ROR) is provided by the PAM50 test.

Methods & findings

This study analyzed the records of 940 women diagnosed with ER+ breast cancer. Additional information collected for each patient included the recurrence score (RS), the risk of recurrence score (ROR), an immuno-histochemical score (IHC4) and a clinical treatment score (CTS). The aim of this study was to determine if these scores were associated with the likelihood of recurrence either in the first 5 years (early recurrence), or 5 to 10 years (late recurrence), after the initial diagnosis. Results showed that of the 940 women, 154 experienced distant recurrence. 71 of the cases were early recurrences and 83 were late recurrences. Lymph node involvement and tumor size were shown to be the only clinical variables providing information regarding the risk of both early and late recurrence. Genetic profiling using the ROR score was the strongest molecular prognostic factor for late recurrence. IHC4 and RS scores were found to be least strongly associated with the risk of late recurrence.

The bottom line

This study provided insight into clinical and molecular factors which may help identify patients who would benefit from extended hormonal treatment beyond 5 years.

Published By: Journal of the National Cancer Institute (JNCI)

Date: Sep 12, 2013

Original Title: Factors Predicting Late Recurrence for Estrogen Receptor-Positive Breast Cancer

Sestak I, et.al. (2013) Factors predicting late recurrence for estrogen receptor-positive breast cancer. J Natl Cancer Inst.105(19):1504-11. doi: 10.1093/jnci/djt244.

Could intraoperative radiotherapy replace standard irradiation treatments?

In a nutshell

This study evaluated the effectiveness of intraoperative radiotherapy as an alternative to standard breast irradiation treatments.

Some background

Breast-conserving surgery followed by whole breast irradiation has become the standard of care in the treatment of small breast cancer tumors. Recent studies have demonstrated that the duration of irradiation can be shortened, and that partial breast irradiation may be employed to reduce the amount of healthy tissue being irradiated, both with similar rates of cancer recurrence.

Intraoperative radiotherapy, in which the tumor bed is given a single-dose of radiotherapy during surgery, is currently under investigation. Intraoperative single-dose radiotherapy is an appealing concept since the burden of multiple weekly treatments is spared. In addition, skin damage, a crucial factor in breast reconstruction, is largely avoided with intraoperative radiotherapy.

Methods & findings

1305 women with early breast cancer were randomized to receive either breast conserving surgery followed by whole breast irradiation, or breast conserving surgery with intraoperative radiotherapy. Women were followed for an average of 5 years to determine the effectiveness of intraoperative radiotherapy in preventing breast cancer recurrences and prolonging survival.

Overall, 35 patients (4.4%) in the intraoperative radiotherapy group and four patients (0.4%) in the external radiotherapy group experienced ipsilateral breast cancer recurrence (local recurrence in the same breast as the original tumor). However, both the rate of metastatic recurrence and overall survival were similar between treatment groups. The 5-year survival rate was 96.8% among women in the intraoperative radiotherapy group and 96.9% among women in the external radiotherapy group. In addition, significantly less skin related side-effects were noted in women undergoing intraoperative radiotherapy, with only 11 women experiencing any type of skin toxicity.

The bottom line

This study concluded that intraoperative single-dose radiotherapy provides a safe and effective treatment alternative to standard breast irradiation.

The fine print

Despite a low rate of local breast cancer recurrence in the intraoperative radiotherapy group, the risk of local recurrence was significantly greater compared to external whole-breast radiotherapy.

Published By: Lancet Oncology

Date: Nov 8, 2013

Original Title: Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): a randomized controlled equivalence trial

Veronesi, U. et.al. (2013). Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): a randomized controlled equivalence trial. The Lancet Oncology, 14(13):1269-1277.doi:10.1016/S1470-2045(13)70497-2.

What can predict cancer recurrence in node-negative patients?

In a nutshell

This study investigated which traits of low-risk breast cancer can predict the risk of cancer recurrence after treatments.

Some background

The majority of women who are diagnosed with breast cancer have node-negative cancer, meaning breast cancer that has not spread to regional lymph nodes. Node-negative breast cancer patients have a low likelihood of cancer recurrence, and are often referred to as low-risk cancer patients. However, some of these patients will experience recurrence. Therefore, it is important to identify breast cancer traits that may predict the risk of recurrence, and treat this subgroup.

Some factors that have been suggested as predictors of recurrence are lymphovascular invasion (LVI; growth of the cancer into nearby blood or lymph vessels) and tumor grade (determined by the appearance of the cancer cells under a microscope; abnormal features represent more aggressive potential of the tumor and have higher grades, scored 1-3).

Methods & findings

Researchers followed 716 node-negative breast cancer patients whose tumors were surgically removed. 47 patients (6.6%) experienced cancer recurrence during an average follow-up period of 4 years.

Patients with LVI were 4 times more likely to experience cancer recurrence compared to patients without evidence of LVI. Patients with grade 3 tumors were 5 times more likely to experience recurrence compared to patients with low-grade tumors. Radiotherapy following surgery was found to eliminate this elevated risk of recurrence for both patients with LVI and grade 3 tumors. Chemotherapy following surgery, however, was not found to reduce this elevated risk.

The bottom line

This study concluded that both lymphovascular invasion and high tumor grade are associated with increased risk of recurrence among node-negative breast cancer patients. In such patients, radiotherapy given after surgery may delay or prevent recurrence.

Published By: The Journal of Surgical Oncology
Date: Aug 31, 2013
Original Title: Clinical and pathologic risk factors of tumor recurrence in patients with node-negative early breast cancer after mastectomy

Lin, P.et.al. (2013), Clinical and pathologic risk factors of tumor recurrence in patients with node-negative early breast cancer after mastectomy. J. Surg. Oncol., 108: 352–357. doi: 10.1002/jso.23403

Everolimus effective and safe in addition to exemestane among elderly women

In a nutshell

This article investigated the safety and effectiveness of everolimus (Afinitor) when used in combination with exemestane (Aromasin) as treatment for elderly women diagnosed with hormone-receptor positive (HR-positive) breast cancer.

Some background

Since HR-positive breast cancers grow in response to estrogen, aromatase inhibitors, which inhibit estrogen production, are often used in the treatment of postmenopausal women diagnosed with breast cancer. Exemestane, a type of aromatase inhibitor is often used as a second-choice drug among women whose disease has already progressed despite hormonal therapy. A recent phase III clinical trial has shown that the addition of everolimus to exemestane significantly extends progression free survival (the amount of time before disease progression) among women being treated with exemestane. However, the effectiveness and safety of this combination treatment has not yet been thoroughly investigated among elderly patients (aged 65-years or more).

Methods & findings

The original phase III trial investigating the addition of everolimus to exemestane included 724 postmenopausal women diagnosed with advanced HR-positive breast cancer. 485 women were randomized to receive combined everolimus and exemestane treatment while the remaining 239 patients received exemestane plus a placebo. Among the participants of the trial 275 women were 65 years of age or older. The addition of everolimus to exemestane appeared to be as beneficial among elderly women when compared to younger patients. Among women 65-years or older, the addition of everolimus to exemestane reduced the risk of disease progression despite treatment by 31%. Among women 70-years or older, the addition of everolimus to exemestane reduced the risk of disease progression despite treatment by 55%. Some adverse events, such as mouth ulcers, lung infections and rashes, occurred more frequently with combined treatment than with exemestane alone. Elderly women did not show any increased incidence of these adverse effects when compared to younger patients. However, more elderly patients required reducing the dose of everolimus during treatments due to adverse events.

The bottom line

This analysis concluded that the addition of everolimus to exemestane is generally well tolerated among elderly breast cancer patients, and appears to provide similar benefits regarding progression free survival.

The fine print

This study was funded by Novartis Pharmaceuticals Co. which manufactures everolimus (Afinitor).

Published By: Clinical Breast Cancer
Date: Dec 1, 2013
Original Title: Safety and Efficacy of Everolimus With Exemestane vs. Exemestane Alone in Elderly Patients With HER2-Negative, Hormone Receptor-Positive Breast Cancer in BOLERO-2.

Medivizor