

## Male breast cancer patients stop taking tamoxifen early because of drug-related side effects

## November 16 2011

The largest study to investigate the tolerability of the breast cancer drug tamoxifen in male breast cancer patients has shown that men stop taking their prescribed therapy early because of problems with side effects caused by the drug.

The authors of the research paper, published today in the cancer journal *Annals of Oncology*, looked at records of 64 male breast cancer patients at their institution who had received tamoxifen for an average of four years and found that 53% (34) of the patients experienced one or more drug-related side effects. Of these 64 patients, 20.3% (13) of the men discontinued taking their prescribed tamoxifen therapy early because of the side effects. The research suggests that male breast cancer patients who discontinue tamoxifen therapy early may have an increased risk of the cancer recurring.

Male breast cancer is a rare disease and the world age-standardised incidence rate is 0.4 per 100,000 in men compared with 66.7 per 100,000 in women. Tamoxifen is the standard of care for the hormone treatment of men with breast cancer and works by blocking the growth-promoting action of the hormone oestrogen on the <u>cancer cells</u>. Almost all (90%) breast cancers in men are hormone-receptor-positive and drugs that target the <u>hormone oestrogen</u> are usually given after surgery.

Dr Naveen Pemmaraju, who carried out the research under the direction



of Dr Sharon Giordano at the Department of Breast Medical Oncology at the University of Texas MD Anderson Cancer Center, Houston, USA, said "This is the largest study to specifically assess tamoxifen-related side effects in men because in our institution we treated a relatively large number of male breast cancer patients. We found that, after adjusting for patient age and stage of the disease, the prognosis for men with breast cancer is similar to that of women. Tamoxifen has been shown to improve survival rates for breast cancer patients, so early discontinuations may have the potential to increase the risk of the cancer recurring in this group of male breast cancer patients.

"Male breast cancer is a very rare and unique cancer affecting approximately 2,000 men in the USA per year. As there are so few male breast cancer cases, clinical practice and optimal treatment strategies have been extrapolated from female breast cancer patients with very little published evidence to guide clinical decisions. In our institution, we noted that several of our male patients were having difficulty with taking tamoxifen therapy, and these side effects appeared to be a little bit different to those reported with women receiving the same drug."

Weight gain and loss of sex drive were the most frequently occurring tamoxifen-related side effects observed in the study. Of the 13 male patients who stopped taking tamoxifen early because of side effects, four of the discontinuation decisions (31%) were physician-directed (four thromboembolic events) and nine (69%) were patient-directed preferences based on the intolerable side-effects. Nine patients died after stopping tamoxifen early in the study.

Dr Pemmaraju said: "Tamoxifen is a hormonal treatment, specifically an anti-oestrogen. We think that men might experience some different side effects than women because men have a different hormonal environment than women (for instance they have more testosterone and less oestrogen). This difference in hormone levels could result in different



side effects when using a drug that blocks hormones.

"The results of this study should not change the recommendation for prescribing tamoxifen for male breast cancer patients. However, clinicians need to be aware of the possible side effects that men may experience when receiving tamoxifen so that the patients can be counselled appropriately," Dr Pemmaraju added. "This study also highlights the importance of funding and conducting research for rare disease so that we understand the true toxicities and benefits of treatment.

"Our next step will be to prospectively collect data on the side effects that men get when they are prescribed to take tamoxifen for breast cancer. This follow-up study will be very important because it will provide much more detailed and comprehensive information on the tolerability profile of tamoxifen in male <u>breast cancer patients</u>," Dr Pemmaraju concluded.

Male breast cancer is very rare and statistical records are not available for most European countries. In the UK, around 300 men are diagnosed with breast cancer each year compared with about 45,700 cases in women. In the US in 2011, about 2,140 new cases of invasive breast cancer will be diagnosed in men compared with 230,480 new cases in women and approximately 450 men will die from breast cancer compared with 39,520 women.

## Provided by European Society for Medical Oncology

Citation: Male breast cancer patients stop taking tamoxifen early because of drug-related side effects (2011, November 16) retrieved 25 April 2024 from <a href="https://medicalxpress.com/news/2011-11-male-breast-cancer-patients-tamoxifen.html">https://medicalxpress.com/news/2011-11-male-breast-cancer-patients-tamoxifen.html</a>



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