

prevented an excess of 40 recurrences, 17 distant recurrences and 14 deaths following recurrence during the first 2.5 years. At 5 years, these figures increased to 82, 44 and 28, respectively. In addition, anastrozole has a generally more beneficial adverse-event profile compared with T, with fewer gynaecological, ischaemic cerebrovascular and venous thromboembolic adverse events.

**Conclusions:** Therefore, initiating T with the intention of changing to an AI after 2 to 3 years (switching) or after 5 years (extended adjuvant) would lose these early benefits of anastrozole over T. Based on current data, offering anastrozole at the earliest opportunity appears to be the best strategy.

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#### Extended role of radioguided occult lesion localization in early stage breast cancer

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**Objective:** Presentation of our experience in radioguided occult lesion localization (ROLL) and sentinel node biopsy with axillary dissection in early stage breast cancer.

**Methods:** Retrospective analysis of clinical, surgical, pathological and oncological data on patients with non-palpable breast lesions treated in Clinical Hospital Split, Croatia, within two years time period. We injected 5–10 MBq of <sup>99m</sup>Tc-labeled colloidal particles of human albumin peritumorally in 102 consecutive patients enrolled in study. The sentinel lymph node in each case was visualized by lymphoscintigraphy. During the surgery, occult breast lesion was localized using ROLL technique and the sentinel lymph node was identified and removed by monitoring the acoustic signal from a hand-held gamma ray-detecting probe. Complete axillary dissection was carried out only in 56 (55%) patients with confirmed pathologic positive sentinel lymph node for micrometastasis.

**Results:** In all the patients non-palpable breast lesion was detected by ROLL. The sentinel lymph node biopsy was identified in 96 (95%) patients. In 56 patients complete axillary dissection was carried out due to positive sentinel node biopsy. There were 5 (5%) false-positive findings. Complication rate in all patients were extremely low (0.5%). All the patients received surgical and adjuvant therapy according to stage, menopausal and receptor status.

**Conclusions:** ROLL followed by sentinel lymph node biopsy using a gamma ray-detecting intraoperative probe allows detecting of occult breast lesions, one step staging of the axilla with high accuracy in patients with primary early stage breast cancer. Axillary dissection may be avoided in patients with negative sentinel node biopsy for micrometastasis. The potential benefits are several: reduced morbidity, definitive surgical treatment performed in a single procedure, improved staging and more rational and selective use of systemic therapy.

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#### 3-year survival of the patients with stage II breast cancer, received an adjuvant hormone therapy with Toremifene (primary results)

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**Background:** Long term research of Oxford Group (EBCTCG) has demonstrated that used an adjuvant hormone therapy with Tamoxifene at the patients with operable breast cancer reduced the incidences of relapses and mortality. According the data of some various trials, use of second generation antiestrogen Toremifene in the adjuvant hormone therapy allows improving results of the treatment of the treatment compared to Tamoxifene. Concerning this, the aim of our clinical research was comparative study of efficiency of an adjuvant hormone therapy with Toremifene and Tamoxifene at the patients with stage II breast cancer.

**Materials and methods:** 181 receptor status not considered patients with stage II breast cancer were involved in this clinical trial. Patients were divided on 3 groups. 61 patients (group I) were treated with Tamoxifene at a dose of 60 mg once daily. Adjuvant hormone therapy with Tamoxifene at a dose of 20 mg once daily was administrated in 63 patients and 57 did not receive hormone therapy. To the patients with normal ovarian function were used castrations by radiotherapy or chemical castration. Patients were treated with adjuvant hormone therapy during all term of observation after radical surgical treatment and adjuvant chemotherapy. All patients were under control no less than 3 year. Efficiency of the treatment determined with following criteria: side effects and 3-year survival without recurrence.

**Results:** In the first group 3-year survival was 93.4%, in the second group 82.5%, in the third group 63.2%. Study of side effects of adjuvant

hormone therapy with Toremifene has demonstrated more safe toxic profile compared to Tamoxifene.

**Conclusions:** The result of this study had indicated higher efficiency and safe toxic profile of adjuvant hormone therapy with Toremifene compared to Tamoxifene. On the base of this data we can recommend Toremifene in adjuvant hormone therapy for the treatment patients with stage II breast cancer.

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#### Toremifen in treatment of precancerous breast diseases

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**Background:** One of the probable mechanisms in the development of dishormonal hyperplasia and breast cancer is hyperestrogenemia on a basis of insufficiency in progesterone. We represent the treatment's results of 46 patients with diffused forms of hyperplasia by a new anti-estrogen drug Toremifen.

**Material and methods:** The age of women was 39–52 years, i.e. premenopausal period. The evidence of hormonal status has shown an authentic increase of estradiol in the luteal phase, reduced contents of progesterone, and moderate hyperprolactinemia. The dose of Toremifen was 30 mg once a day, during 1 month.

**Results:** Clinical improvement was found in 35 patients (76.1%), in 9 patients the use of this drug was stopped, due to menstrual disorders, 2 patients had intermenstrual bleeding. A softening, reduction of intensity and decrease of pain in the breast was marked. Hormonal status has shown authentic decrease in estradiol, increase in progesterone in the second phase of the menstrual cycle, however compensational increase of prolactin was noted. In 2 patients with tendention to located forms of hyperplasia, a decrease of focal condensation to complete disappearance was marked in 4 cases. In ultrasonic examination of the breast we have noted a reduction in the density of fibrotic component, reduction in diameter of small cystical formations. The clinical effect of one month's treatment with Fareston lasts 3 to 4 months.

**Conclusions:** We would like to emphasize that the high efficacy and good tolerance of Toremifen make it possible to administer such drug in the combined treatment of mastopathy in women with survived menstrual-ovarian function.

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#### Efficiency of Toremifen in the treatment of diffuse mastopathy

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**Background:** Diffuse mastopathy is the most common disease of breast of women. By the data of various authors the frequency of mastopathy occurs at the reproductive females is 24–40%. The rate of annual morbidity increase is 8–10%. The pathogenetical treatment of diffuse mastopathy is therapy with hormonal drugs. The aim of the research was comparative study of efficiency of Toremifen in the complex therapy of patients with diffuse mastopathy.

**Materials and methods:** 254 patients with diffuse mastopathy were involved in this trial. Patients were divided on 2 groups. Patients of first group (n = 136) were treated with Toremifen at a dose of 20 mg once from 5th to 25th day of regular menstrual cycle or daily with impaired menstrual function and in menopause. The patients of second group (n = 118) were treated by phytotherapy. Duration of treatment in both group patients was 6 months. Efficiency of the treatment was determined with following criteria: dynamics of pain syndrome and changes of mammographic density of breast.

**Results:** In the group of patients treated with Toremifen 122 (89.7%) patients had complete response, which was defined as the disappearance of any pain, 14 (10.3%) had reduction of pain. In the group of patients treated by phytotherapy, results were following: 22 (18.7%) patients had complete response, which was defined as the disappearance of any pain, 64 (54.2%) had reduction of pain, 32 (27.1%) had no response. The dynamics of changes of mammographic density in breast was following: in the first group 92 (67.6%) patients had the normal mammography, 29 (21.3%) patients had reduction of indurations, 15 (11.1%) patients had no changes in mammography. The results of second group patients were following: 11 (9.3%), 25 (21.2%) and 82 (69.5%) patients respectively.

**Conclusions:** The results of our study had demonstrated high efficiency of Toremifen compared to phytotherapy in the treatment of diffuse mastopathy.