Reduced Side-effects of Adjuvant Hormone Therapy in Breast Cancer Patients by Complementary Medicine

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Abstract. A clinical investigation (representing evidence-based medicine level III) was performed to evaluate the benefit of complementary medicine in breast cancer patients undergoing adjuvant hormone therapy (HT). Patients and Methods: The patients (n=129) were treated according to international guidelines. All patients suffered from arthralgia and mucosal dryness induced by the adjuvant HT. To reduce these side-effects, the patients were complementarily treated with a combination of sodium selenite, proteolytic plant enzymes (bromelaine and papain) and Lens culinaris lectin. On the basis of case report formulas (CRFs), self assessment of defined side-effects of HT (arthralgia and mucosal dryness) were documented before as well as 4 and 8 weeks after complementary treatment. Validation was carried out by scoring from 1 (no side-effects/optimal tolerability) to 6 (extreme side-effects/extremely bad tolerability). Results: The severity of side-effects of HT was reduced by complementary treatment with sodium selenite, proteolytic plant enzymes (bromelaine and papain) and Lens culinaris lectin. The mean score of symptoms declined from 4.2 (before treatment) to 3.2 (after 4 weeks of treatment) to 2.7 (after 8 weeks of treatment) for arthralgia and from 3.2 (before treatment) to 2.9 (after 4 weeks of treatment) to 2.6 (after 8 weeks of treatment) for mucosal dryness, the primary aims of this investigation. The reduction of side-effects of HT was statistically significant (p<0.001 after 4 weeks and p<0.0001 after 8 weeks). Conclusion: This investigation demonstrates benefits of indication-based complementary treatment with the combination of sodium selenite, proteolytic enzymes and Lens culinaris lectin into evidence-based medicine.

Breast cancer is the most common cause of cancer death in women worldwide. Overall, the incidence of breast cancer rises with age, increasing rapidly during the fourth decade of life and continuing to increase thereafter, but more slowly in the fifth, sixth and seventh decades (1).

Cancer demands diagnostic and therapeutic measures with proven quality, safety and efficacy. The basis for evidence-based treatment is the randomized controlled trial (RTC). In this regard, surgery, chemotherapy (CT), radiotherapy (RT), and HT have emerged as gold standards in the treatment of cancer. Only these therapies have proven their cancer destructive potencies and their curative feasibility, dependent on cancer entity and stage (2, 3).

Evidence-based treatments of breast cancer follows recommendations of international expert panels. They are regularly updated during conferences and comprise indication-based surgery, CT, RT, and HT (4, 5). CT and RT are known to induce a broad range of side-effects, e.g. arthralgia and mucosal dryness (6, 7). The standard adjuvant endocrine therapy for women with hormone receptor-positive breast cancer is also often restricted by severe side-effects such as mucosal dryness, arthralgia and vascular events (8, 9).

HT for breast cancer treatment exerts anti-estrogenic properties within the breast and in mucosal tissue. Lack of estrogen causes thinning of mucosal linings, mucosal dryness and inflammation (10). Recently, a clinical investigation demonstrated an enhanced tolerability to CT and RT of breast cancer patients that were complementarily treated with a combination of sodium selenite, plant enzymes and Lens culinaris lectin due to decreased side-effects such as mucosal dryness and arthralgia (6, 7). Since reduced function of mucosal linings and correlating symptoms (e.g. arthralgia, mucosal dryness) result from cytotoxic effects of CT or RT and from hormone depletion (6, 7, 9, 10), these distinct side-effects were chosen as primary aims of this investigation.
Complementary medicine is popular all over the world. The American Cancer Society defines complementary medicine or methods as those that are used along with regular medical care (11). If these treatments are carefully chosen and managed, they may enhance comfort and well-being (6, 7). Some complementary treatments have been tested, e.g. nutrition, sports, psychooncology (6, 7). Certain complementary medications such as sodium selenite and proteolytic enzymes have shown clinical benefits in randomized controlled trials, e.g. reduced adverse reactions of CT and RT, enhanced quality of life (12-14), while others, e.g. Lens culinaris lectin are traditional naturopathic remedies to stabilize the mucosal surfaces (15).

This clinical investigation was performed to evaluate the safety and efficacy of complementary sodium selenite, proteolytic enzymes and Lens culinaris lectin treatment to reduce defined side-effects (namely mucosal dryness, arthralgia) of guideline-based HT in breast cancer patients.

**Patients and Methods**

**Patients.** Women with histologically verified breast cancer undergoing adjuvant HT (according to the actual St. Gallen recommendations) were enrolled in this investigation. All patients suffered from severe side-effects (mucosal dryness and arthralgia) of the HT which were initially validated and documented.

**Complementary treatment.** The patients (n=129) were complementarily treated with an oral medication (Equizym MCA; MK-Pharma, Valkenburg, the Netherlands; Reg. Nr. 6640019) containing sodium selenite (300 μg/day), proteolytic enzymes (bromelaine 2000 units/day and papain 2000 units/day) and Lens culinaris lectin (20 mg/day). Complementary treatment to HT was continued for 8 weeks. Safety and efficacy of sodium selenite and proteolytic enzymes were extensively investigated in randomized controlled trials (12, 13). Their combination with Lens culinaris lectin (15) was found to be an innovative and beneficial complementary approach to stabilize mucosal linings (6, 7). Other complementary remedies, especially antioxidative vitamins and trace elements and immunoactivation, were not taken by the patients throughout this investigation.

**Side-effects of HT.** Case report formulas (CRFs) were used to document self assessed safety and efficacy of the complementary treatment. Patients were assessed routinely before, as well as 4 and 8 weeks after terminating the complementary therapy. The efficacy of the complementary treatment was verified by questioning the severity of side-effects such as mucosal dryness and arthralgia (as primary aims of this investigation). Severity of symptoms was quantified by scoring from 1 (no side-effects) to 6 (extreme side-effects). An average score was calculated for symptoms of the adjuvant therapy to investigate the value of this complementary treatment.

**Statistics.** Student’s *t*-test was performed to calculate statistical significance between mean values of scores for side-effects of HT after 4 and 8 weeks of complementary treatment.

**Results**

A total of 129 evaluable breast cancer patients were enrolled into this clinical investigation. All patients (mean age 50.5 years) suffered from mucosal dryness and arthralgia induced by HT. Basic clinical parameters of the patients are shown in Tables I and II.

**Adverse reactions of the complementary medication (sodium selenite, proteolytic enzymes and Lens culinaris lectin)** were investigated by self assessment. As shown in Table III the severity of the side-effects mucosal dryness and arthralgia was reduced significantly (*p*<0.001 after 4 weeks and *p*<0.0001 after 8 weeks) after the onset of complementary treatment. Concerning mucosal dryness, this symptom was significantly reduced in eyes and vagina. These results demonstrate that an efficient management of adverse reactions of adjuvant HT in breast cancer patients is possible by well-defined complementary medicine.

**Side-effects of HT.** Case report formulas (CRFs) were used to document self-assessed safety and efficacy of the complementary treatment. Patients were assessed routinely before, as well as 4 and 8 weeks after terminating the complementary therapy. The efficacy of the complementary treatment was verified by questioning the severity of side-effects such as mucosal dryness and arthralgia (as primary aims of this investigation). Severity of symptoms was quantified by scoring from 1 (no side-effects) to 6 (extreme side-effects). An average score was calculated for symptoms of the adjuvant therapy to investigate the value of this complementary treatment.

**Statistics.** Student’s *t*-test was performed to calculate statistical significance between mean values of scores for side-effects of HT after 4 and 8 weeks of complementary treatment.
This clinical investigation was performed to evaluate the safety and efficacy of an innovative complementary medication composed of sodium selenite, proteolytic enzymes and *Lens culinaris* lectin. Whereas sodium selenite and proteolytic enzymes have proven their clinical safety and efficacy in controlled trials (12, 13), *Lens culinaris* lectin was added to the medication because of its stabilizing effects on mucosal surfaces (15). The scientific rationale of this complementary treatment is: enhancement of the tolerability to HT by reduction of defined adverse reactions to optimize this guideline-based therapy. This investigation shows that complementarily administered sodium selenite, proteolytic enzymes and *Lens culinaris* lectin significantly reduced defined side-effects of adjuvant HT in breast cancer patients. The reduced adverse reactions of HT, namely arthralgia and mucosal dryness, clearly lead to enhanced tolerability and compliance.

Since the tolerability of adjuvant HT determines its optimal administration, complementary treatment with sodium selenite, proteolytic enzymes and *Lens culinaris* lectin may enhance the chance of curing the disease.

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References


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