

Uterine Fibroids

ABSTRACTS

ATAC Trialists' Group., 2002. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial.

Gerhard I., 1992. [The limits of hormone substitution in pollutant exposure and fertility disorders]

Golan A., 1996. GnRH analogues in the treatment of uterine fibroids.

Goldin BR., 1982 . Estrogen excretion patterns and plasma levels in vegetarian and omnivorous women.

Marshall LM., 1998. A prospective study of reproductive factors and oral contraceptive use in relation to the risk of uterine leiomyomata.

Pollow K., 1978. Estrogen and progesterone binding proteins in normal human myometrium and leiomyoma tissue.

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Eldar-Geva T, 1998. Other medical management of uterine fibroids.

Fruscella L., 1997. [Vitamin E in the treatment of pregnancy complicated by uterine myoma].

Kadry M., 1999. Pulmonary leiomyomatosis in women after hysterectomy for uterine myoma. Benign metastasizing leiomyoma?

Shaw RW., 1989. Mechanism of LHRH analogue action in uterine fibroids.

Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial.

ATAC Trialists' Group. Baum M, Budzar AU, Cuzick J, Forbes J, Houghton JH, Klijn JG, Sahmoud T; ATAC Trialists' Group.

Lancet. 2002 Jun 22;359(9324):2131-9.

BACKGROUND: In the adjuvant setting, tamoxifen is the established treatment for postmenopausal women with hormone-sensitive breast cancer. However, it is associated with several side-effects including endometrial cancer and thromboembolic disorders. We aimed to compare the safety and efficacy outcomes of tamoxifen with those of anastrozole alone and the combination of anastrozole plus tamoxifen for 5 years.

METHODS: Participants were postmenopausal patients with invasive operable breast cancer who had completed primary therapy and were eligible to receive adjuvant hormonal therapy. The primary endpoints were disease-free survival and occurrence of adverse

events. Analysis for efficacy was by intention to treat.

FINDINGS: 9366 patients were recruited, of whom 3125 were randomly assigned anastrozole, 3116 tamoxifen, and 3125 combination. Median follow-up was 33.3 months. 7839 (84%) patients were known to be hormone-receptor-positive. Disease-free survival at 3 years was 89.4% on anastrozole and 87.4% on tamoxifen (hazard ratio 0.83 [95% CI 0.71-0.96], $p=0.013$). Results with the combination were not significantly different from those with tamoxifen alone (87.2%, 1.02 [0.89-1.18], $p=0.8$). The improvement in disease-free survival with anastrozole was seen in the subgroup of hormone-receptor-positive patients, but not the receptor-negative patients. Incidence of contralateral breast cancer was significantly lower with anastrozole than with tamoxifen (odds ratio 0.42 [0.22-0.79], $p=0.007$). Anastrozole was significantly better tolerated than tamoxifen with respect to endometrial cancer ($p=0.02$), vaginal bleeding and discharge ($p<0.0001$ for both), cerebrovascular events ($p=0.0006$), venous thromboembolic events ($p=0.0006$), and hot flushes ($p<0.0001$). Tamoxifen was significantly better tolerated than anastrozole with respect to musculoskeletal disorders and fractures ($p<0.0001$ for both).

INTERPRETATION: Anastrozole is an effective and well tolerated endocrine option for the treatment of postmenopausal patients with hormone-sensitive early breast cancer. Longer follow-up is required before a final benefit:risk assessment can be made.

[The limits of hormone substitution in pollutant exposure and fertility disorders] [Article in German]

Gerhard I, Runnebaum B. Abteilung für Gynäkologische Endokrinologie und Fertilitätsstörungen, Universitätsfrauenklinik Heidelberg.

Zentralbl Gynakol 1992;114(12):593-602

Heavy metals and chloro-organic compounds can influence female fertility at every phase of reproduction. They may induce hormonal disorders, preventing ovulations and pregnancies. They can also result in abortions and fetal malformations. For this reason, the urinary excretion of heavy metals was measured after oral load with the chelating agent dimercaptopropanesulfonate (Dimaval) in women with hormonal irregularities. In addition, blood was examined for various polychlorinated compounds (polychlorinated biphenyls - PCB -, hexachlorocyclohexane - HCH -, pentachlorophenole - PCP -, hexachlorobenzol - HCB -, dichlordiphenyltrichloroethane - DDT -, dichlorodiphenylethane - DDE -, tetrachlorodiphenylethane - DDD -). Mercury contaminations were seen most commonly and correlated significantly with the number of amalgam fillings and with the release of mercury while chewing. The latter was demonstrated with the so-called chewing-gum test. Women with hormonal disorders or alopecia had, on the average, the highest mercury excretion during the wash-out test. Cadmium excretion was pronounced for the following groups of women: those with technical professions, those suffering from thyroid dysfunctions, and those with habitual abortions and uterine fibroids. With increasing age, pesticide concentrations of the blood rose significantly. Women with endometriosis and with antihyroidal antibodies had significantly higher PCB values. Despite therapeutic intervention, fewer women with elevated DDT/DDE/DDD values conceived when compared to those with lower values. alpha-HCH concentrations were often elevated in women with uterine fibroids. With increasing PCP levels pregnancies often ended in abortion. Results of this investigation indicate that women with hormonal irregularities or specific fertility disorders should be examined for heavy metal and pesticide contamination prior to hormone treatment.

GnRH analogues in the treatment of uterine fibroids.

Golan A. Department of Obstetrics and Gynecology, Assaf Harofeh Medical Center, (Affiliated to Sackler Faculty of Medicine, Tel-Aviv University, Zerifin, Israel.

Hum Reprod 1996 Nov;11 Suppl 3:33-41

It is now known that gonadotrophin-releasing hormone analogues (GnRHa) are extremely efficient at reducing uterine fibroid volume and reversing the related symptomatology. However, the fibroids tend to return to their pretreatment size about 6 months after discontinuing treatment. GnRHa treatment cannot be continued indefinitely due to its potential complications and high cost. It is therefore proposed that GnRHa treatment should be phase one of a two-phase treatment plan for uterine fibroids. The initial course of GnRHa should be followed by either menopause or surgery. Experience with presurgical GnRHa use indicates a definite treatment advantage and the use of GnRHa as adjuncts to surgery is well established. The value of GnRHa treatment as an alternative to surgery in pre-menopausal patients, however, remains to be established.

Estrogen excretion patterns and plasma levels in vegetarian and omnivorous women.

Goldin BR, Adlercreutz H, Gorbach SL, Warram JH, Dwyer JT, Swenson L, Woods MN.

N Engl J Med 1982 Dec 16;307(25):1542-7

We studied 10 vegetarian and 10 nonvegetarian premenopausal women on four occasions approximately four months apart. During

each study period, the participants kept three-day dietary records, and estrogens were measured in plasma, urinary, and fecal samples. Vegetarians consumed less total fat than omnivores did (30 per cent of total calories, as compared with 40 per cent) and more dietary fiber (28 g per day, as compared with 12 g). There was a positive correlation between fecal weight and fecal excretion of estrogens in both groups (P less than 0.001), with vegetarians having higher fecal weight and increased fecal excretion of estrogens. Urinary excretion of estriol was lower in vegetarians (P less than 0.05), and their plasma levels of estrone and estradiol were negatively correlated with fecal excretion of estrogen ($P = 0.005$). Among the vegetarians the beta-glucuronidase activity of fecal bacteria was significantly reduced ($P = 0.05$). We conclude that vegetarian women have an increased fecal output, which leads to increased fecal excretion of estrogen and a decreased plasma concentration of estrogen.

A prospective study of reproductive factors and oral contraceptive use in relation to the risk of uterine leiomyomata.

Marshall LM, Spiegelman D, Goldman MB, Manson JE, Colditz GA, Barbieri RL, Stampfer MJ, Hunter DJ. Department of Epidemiology, Harvard School of Public Health, Boston, Massachusetts, USA.

Fertil Steril 1998 Sep;70(3):432-9

OBJECTIVE: To investigate the risk of uterine leiomyomata in relation to reproductive factors and oral contraceptive use.

DESIGN: A prospective study.

SETTING: A cohort of female registered nurses from 14 states in the United States who completed mailed questionnaires in 1989, 1991, and 1993.

PATIENT(S): Premenopausal nurses ($n=95,061$) aged 25-42 years with intact uteri and no history of diagnosed uterine leiomyomata or cancer in 1989.

INTERVENTION(S): None.

MAIN OUTCOME MEASURE(S): Incidence of self-reported uterine leiomyomata confirmed by ultrasound or hysterectomy. In a sample of 243 cases, 93% of the self-reported diagnoses were confirmed in the medical record.

RESULT(S): During 326,116 person-years of follow-up, 3,006 cases of uterine leiomyomata, confirmed by ultrasound or hysterectomy, were reported. After adjustment for other risk factors, the risk of uterine leiomyomata was significantly inversely associated with age at menarche, parity, and age at first birth, and positively associated with a history of infertility and years since last birth. The only notable association with any aspect of oral contraceptive use was a significantly elevated risk among women who first used oral contraceptives at ages 13-16 years compared with those who had never used oral contraceptives.

CONCLUSION(S): Reproductive factors and oral contraceptive use at a young age influence the risk of uterine leiomyomata among premenopausal women. operations were vaginal excision of the submucous myomata protruding into the cervix during treatment, and in five hysterectomy performed because of persistence of symptoms. In most patients the achievement of amenorrhoea minimized the fear of surgical emergency, facilitating an increased awareness of their clinical condition. With the exception of the three patients who dropped out, side effects were mild in all patients, consisting mainly of hot flushes, which were easily tolerated. In the following 8-12 months, the regrowth of uterine volume to original size has been usual in most of the 82 patients now in follow-up.(ABSTRACT TRUNCATED AT 400 WORDS)

Estrogen and progesterone binding proteins in normal human myometrium and leiomyoma tissue.

Pollow K, Geilfuss J, Boquoi E, Pollow B.

J Clin Chem Clin Biochem 1978 Sep;16(9):503-11

The occurrence and characteristics of macromolecular components of normal human myometrium and leiomyoma which bind [3 H] estradiol and [3 H]progesterone were investigated, employing dextran coated charcoal, density gradient centrifugation and gel filtration techniques. On sucrose density gradient centrifugation, [3 H]progesterone was bound by macromolecules with sedimentation rates of about 4 S and 8 S. The major [3 H]progesterone binding component had a sedimentation coefficient of about 4 S, which contained specific and nonspecific binding sites. Sedimentation patterns as well as elution profiles from agarose gel revealed a striking similarity between biochemical properties of the progesterone receptors from normal myometrium and leiomyomas of the same organ. Both progesterone and estradiol receptor change in concentration during the normal menstrual cycle. During the early proliferative phase the number of estradiol receptor binding sites was highest; after ovulation, a rapid decrease of estradiol receptor level was seen. On the other hand, using [3 H]progesterone as the ligand, the highest receptor concentration was found at midcycle. The leiomyoma steroid hormone receptor levels were compared with those in normal

myometrium. Whereas leiomyoma exhibited higher estradiol binding capacity, the concentration of progesterone receptors was low in fibroid tumors.

Oestrogen and progesterone receptor concentrations in leiomyoma and normal myometrium.

Sadan O, van Iddekinge B, van Gelderen CJ, Savage N, Becker PJ, van der Walt LA, Robinson M.

Ann Clin Biochem 1987 May;24 (Pt 3):263-7

The content of cytoplasmic 17 beta oestradiol and progesterone receptors in human uterine leiomyoma and normal myometrium in the Negroid population was determined. Eighteen women of reproductive age, at various stages of the menstrual cycle, were included in the study. The serum oestrogen and progesterone concentrations were also measured. This is the first report in the literature in which oestrogen and progesterone receptors in leiomyoma are significantly higher than in normal myometrium ($P = 0.0002$). The steroid dependence of the growth of leiomyomas may be related to the steroid receptor level. The presence of persistently high concentrations of oestrogen and progesterone receptors in leiomyoma should be helpful in the treatment of this benign tumour.

Efficacy of leuprorelin acetate depot in symptomatic fibromatous uteri: the Italian Multicentre Trial.

Serra GB, Panetta V, Colosimo M, Romanini C, Lafuenti GB, Garcea N, Votano S, Agatensi L. Ospedale Cristo Re, Rome, Italy.

Clin Ther 1992;14 Suppl A:57-73

A total of 110 nonmenopausal women (mean age 42.1 years) presenting with symptomatic uterine leiomyomata and/or fibromatous uteri have been enrolled in this trial to evaluate the efficacy of the depot formulation of leuprorelin acetate in decreasing uterine volume and minimizing menorrhagia, dysmenorrhoea and pressure over the bladder. All patients were treated with an intramuscular injection of leuprorelin acetate depot 3.75 mg every 4 weeks for 16 weeks. Clinical examinations and hormonal and ultrasound determinations were performed before, during and at the end of treatment. Appropriate follow-up is still ongoing for most patients. At the end of the treatment period, of 88 women with enlarged fibromatous uteri, 33 (37.5%) showed a decrease in uterine volume of greater than or equal to 50% of the original size, while nine (10.2%) remained with unchanged uterine volume. Of 80 fibromas measurable separately, 47 (52.8%) decreased by greater than 50% of the initial volume and 16 (18%) remained unchanged or even increased. During treatment, clinically advantageous effects were observed in the associated symptomatology, mainly in the production of amenorrhoea and restoration of normal haemoglobin levels. Most of the patients were affected by irregular menstrual blood loss with consequent anaemia that in 29 patients was expressed by low levels of haemoglobin (mean 9.2 g/dl; SD 1.5; range 4.5-11.8 g/dl). By the end of the treatment, only one patient still had moderate vaginal blood loss. Haemoglobin levels rose to a mean value of 11.8 g/dl (SD 1.3; range 8.5-14.1 g/dl). Three patients (2.7%) failed to complete the 16-week treatment protocol, because of headache (one patient) and increased blood pressure (two patients). As a result of the treatment, of the 107 patients who were candidates for surgery and who were included in this study, only nine (8.4%) required surgery during leuprorelin acetate treatment.

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Experience with leuprorelin acetate depot in the treatment of fibroids: a German multicentre study.

Cirkel U, Ochs H, Schneider HP, Mettler L, Mayer-Eichberger D, Schindler AE, Buhler K, Winkler U, Zahradnik HP, Kunzig HJ, et al. Universitäts-Frauenklinik Munster, Germany.

Clin Ther 1992;14 Suppl A:37-50

Between October 1988 and October 1990 in a noncomparative multicentre study, 114 patients were treated for uterine fibroids with the gonadotrophin-releasing hormone (Gn-RH) agonist, leuprorelin acetate depot. The mean age of the women was 33 years and 55.3% of them had a history of infertility. After confirmation of the diagnosis by ultrasound and/or operation, treatment began between day 1 and 3 of the cycle with leuprorelin acetate depot 3.75 mg subcutaneously. Therapy was carried out for a total of 6 months with one injection every 4 weeks. Treatment was paralleled by measurements of endocrine and metabolic parameters, estimation of myoma and uterine size by ultrasound and self-reporting of the patients of drug-related complaints. Four of the 114 women did not complete the whole treatment, two of them because of general side effects, one because of carcinophobia and unsatisfactory regression of the myoma and the last one for unspecified reasons. During treatment, a mean reduction of the uterine volume of about 67% was observed, in conjunction with shrinkage of the myoma in 92.1% of cases (mean decrease of 56% of the fibroids) with a large interindividual difference. Maximal diminution of uterine and fibroid size had been nearly completely reached within the first 12 weeks of therapy. After 4 weeks of the Gn-RH agonist depot most of the patients had achieved postmenopausal status, which continued throughout the remaining 20 weeks of treatment. In accordance with this finding, the majority of general side effects was due to the hypo-oestrogenic endocrine status. Liver and lipid metabolism was almost unaffected, although increasing calcium and alkaline phosphatase serum levels as well as an increased urinary calcium/creatinine ratio demonstrated an increased metabolic turnover of the bone. Haemoglobin concentrations, however, increased in those cases with fibroid-related anaemia. Thus the slow-release form of leuprorelin acetate is an adjunct to myomectomy especially in those women in whom family planning is not yet completed.

Other medical management of uterine fibroids.

Eldar-Geva T, Healy DL. Monash IVF, Epworth Hospital, Victoria, Australia.

Baillieres Clin Obstet Gynaecol 1998 Jun;12(2):269-88

Several medicines are emerging with the potential to treat symptomatic uterine fibroids. Anti-progesterone compounds seem particularly promising. These drugs have been widely used for nearly 20 years and are known to be safe; medical politics have prevented their proper investigation for uterine fibroids. In particular, the value of mifepristone, 50 mg per day for 3 months, seems particularly promising. Further investigation is clearly warranted for this medicine. Several anti-oestrogen compounds have recently become available and may also be useful for the medical treatment of symptomatic uterine fibroids. This includes the possibility of the use of selective oestrogen receptor modulators as well as the prospect of the use of pure anti-oestrogens. On a longer time frame, inhibitors of angiogenesis may be useful. These medicines would act upon the blood supply to uterine fibroids. Physicians also have an obligation to investigate scientifically any promising naturopathic treatment that appears to have possible activity for symptomatic fibroids.

[Vitamin E in the treatment of pregnancy complicated by uterine myoma] [Article in Italian]

Fruscella L, Ciaglia EM, Danti M, Fiumara D. Divisione di Ostetricia e Ginecologia, USL RM/B, Ospedale S. Pertini, Roma.

Minerva Ginecol 1997 Apr;49(4):175-9

The authors describe the encouraging results obtained in the treatment of uterine myomas during pregnancy, using vitamin E at a dose of 300 mg times a day, starting the administration from the time of the first examination of the patient, which took place between week 6 and 12 of gestation. A group of 25 women underwent treatment, aged between 25 and 41 years old, of whom 15 were primigravidas and 10 with one or more previous pregnancies, suffering from uterine myomas in pregnancy, and observed between 1986 and 1994. All the pregnancies continued to term and elective cesarean section was performed associated with single or multiple myomectomy. The neonatal outcome was satisfactory in all cases and no collateral effects were observed in either mothers or fetuses.

Pulmonary leiomyomatosis in women after hysterectomy for uterine myoma. Benign metastasizing leiomyoma?

Kadry M, Sievers C, Engelmann C. Clinic for Thoracic Surgery, Special Clinic for Pulmonology and Thoracic Surgery, Berlin, Germany.

Acta Chir Hung 1999;38(1):57-61

INTRODUCTION: Leiomyomas, which usually occur multilocular in uterus, can develop even if rarely in other organs with smooth muscle cells. The tumour is considered benign; 2 case reports supports the hypothesis that uterus myoma could metastasize, and in the metastasis sites grow invasively.

METHODS: 2 female patients 44 y. and 29 y. old were admitted to our clinic for MPL. Due to increasing tumor size respectively dyspnea, they were operated on. Multiple nodules of the left lung in one case, and a mediastinal tumour in the other were resected; resected tumour was histologically examined.

RESULTS: In both cases it was a matter of well-differentiated leiomyosarcoma. The mediastinal tumour has already invade the N. phrenicus. Postoperatively there were no complications. Patients discharged in well-doing state, medical control one year later revealed no new growth.

CONCLUSION: Multiple pulmonary leiomyomas are rare, they occur in sexually mature women in coincidence with uterus myoma. Even though many authors assume that MPL is a lung metastasis of benign tumours, the pathogenesis is still hypothetical. Supporting this thesis is the hormone dependence of both the uterine and the pulmonary tumours; against it, is that extrapulmonary locations are too rarely observed. The still open pathogenetical question has no therapeutical consequence. Whenever technically possible, a radical, parenchyma-saving surgical therapy should be the first choice. Otherwise hormon-ablation is a good alternative.

Mechanism of LHRH analogue action in uterine fibroids.

Shaw RW. Academic Department of Obstetrics and Gynaecology, Royal Free Hospital School of Medicine, London, UK.

Horm Res 1989;32 Suppl 1:150-3

Luteinising hormone-releasing hormone analogues have been found to reduce the size of uterine fibroids. Further studies are required to determine their exact mechanism of action. However, they are known to induce hypo-oestrogenism, which leads to reduction in uterine arterial blood flow, one mechanism by which reduction of fibroid size is thought to occur.

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