441 ORAL

Do improved outcomes of breast cancer in participants to clinical trials result from better treatment, selective referral, or both?

N. Hébert-Croteau[1,2], J. Brisson[1,3], J. Lemaire[2], J. Latreille[2]. [1]*Institut national de santé publique du Québec, Direction des systèmes de soins et services, Montréal, Québec, Canada* [2]*Hôpital Charles LeMoyne, Centre de recherche, Greenfield Park, Québec, Canada* [3]*Université Laval, Unité de recherche en santé des populations, Québec, Québec, Canada*

Background: It is assumed that individuals who participate to clinical research have more favorable outcomes of their disease than others. Factors responsible for this relationship are unclear, since improved survival could result either from better care or from selective enrolment of patients with more favorable prognosis at baseline. The goal of this analysis was to evaluate the relative contribution of these factors to the survival of women participating to clinical trials for the primary therapy of their breast cancer.

Materials and methods: The study population included women newly diagnosed with node-negative breast cancer in Québec, Canada, between 1988 and 1994. Information on the patient, her disease, the source of care, treatment, enrolment in multicenter clinical trials, recurrences and deaths was collected by chart review. Vital status was also updated by linkage with the mortality and other databases and by queries to attending physicians. End of follow-up was December 31, 1999. Guidelines for systemic treatment from the 1992 St-Gallen consensus conference were used to define compliance with standards of care. Women under experimental protocol were compared to those who did not participate to research, and received or not treatment consistent with guidelines, using Cox proportional hazards analysis.

Results: The study population included 1727 women with median follow-up of 6.8 years. Actuarial estimate of 7-year overall survival was 82% (95% confidence interval (c.i.): 80%,84%). As compared to women who were not under experimental protocol and did not receive systemic treatment consistent with guidelines (n=381), those who enrolled in a clinical trial (n=207) had a hazard ratio of death of 0.45 (95% c.i.: 0.27,0.73), after adjustment for year of diagnosis, age, co-morbidity, tumor grade, estrogen receptor status, stage, as well as loco-regional treatment. Women who did not participate to research but received treatment consistent with guidelines (n=951) had a hazard ratio of death of 0.70 (95% c.i.: 0.54,0.90).

Conclusions: Participation to clinical trials confers a gain in survival at least as great as compliance with current standards of care. Women derive substantial benefit from this participation and treatment centers should be encouraged to become affiliated to the networks of collaborating institutions.

442 ORAL

Attitude towards the prevention of breast cancer – results of a survey of women with an average risk of breast cancer (n=7000) and free-practising gynaecologists (n=800) in Germany

S. Paepke[1,2], G. von Minckwitz[2], M. Kaufmann[2], G. Raab[2], G. Heinrich[2], R.K. Schmutzler[2], J. Torode[2], P. Maier[2], V.R. Jacobs[1], M. Kiechle[1,2]. [1]*Technical University Munich, Frauenklinik (OB/GYN), Munich, Germany;* [2]*IBIS II Study Group, Germany*

Introduction: The updated meta-analysis of randomised tamoxifen preventions studies shows a 38% reduction in the incidence of breast cancer (Odds Ratio 0.62; 95% CI 0.42–0.89). The International Breast Intervention Study (IBIS II) compares anastrozole and placebo with the aim of improving the therapeutic index.

In Germany, pharmacological prevention can currently only be recommended under the conditions of a clinical study. In contrast to comparable international studies, participation of women at an increased risk in breast cancer prevention studies is problematical. The question is what are the underlying factors. To analyse them, the attitude of both women at an average risk of breast cancer and gynaecologists, as their most important contact persons, was assessed.

Material and Methods:

i. During a visit to their gynaecologist, 7000 women were asked to complete a questionnaire on their awareness of and readiness for pharmacological prevention. The return rate of the questionnaires was 82.5%.

ii. In preparation of the start of the IBIS II Study (a comparison of anastrozole vs. placebo), a questionnaire was sent to 800 free-practising gynaecologists in Germany. 154 completed questionnaires were entered in the first analysis of 10/03.

Results: 19.5% of the women surveyed on the occasion of a visit to their gynaecologist knew about the possibility and 55.3% would take medications for prevention. The distribution is almost identical in the various regions of Germany (Table 1).

Table 1. Attitude of women at an average risk of breast cancer towards pharmacological prevention (Question: "Would you take medications for prevention?")

	Düsseldorf	Frankfurt	Göttingen	Kiel	Berlin	Hildesheim	Total
Number	1044	659	147	721	885	161	3598
%	53.8	58.8	59.9	55.8	54.9	48.8	55.3

Table 2. Attitude of free-practising gynaecologists towards the prevention of breast cancer.

		YES Number	%
I	Do changes in the way of life and nutrition have an influence on the incidence of breast cancer?	127	82.47
II	Is pharmacological prevention of breast cancer principally possible?	90	58.44
III	Would you recommend pharmacological prevention?	67	43.51
IIIa	To every women?	18	26.87
IIIb	To elderly women?	18	26.87
IIIc	To women with family history?	62	92.54
IV	Would you tend to recommend pharmacological prevention when asked by a patient?	54	35.06

Discussion: Changes in the way of life and nutrition are regarded as important for the prevention of breast cancer. More than half the doctors asked believe that pharmacological prevention is possible. Acceptability by women also exceeds 50%. Nevertheless, a considerably lower proportion of gynaecologists would recommend pharmacological prevention, and part of them would even recommend against it.

Conclusion: The majority of the women asked are motivated, while gynaecologists are rather sceptical towards pharmacological prevention. Therefore, enormous information work must be done and an infrastructure with leading centres be created in order to achieve a nation-wide coverage of all women interested in pharmacological prevention as part of the IBIS II Study.

Additional information can be found at www.brustkrebsvorbeugen.de.

This survey was supported by AstraZeneca.

443 ORAL

Development of network of cancer family syndrome registries in Eastern Europe

J. Lubinski. *Pomerian Medical University, Szczecin, Poland*

Project participants: Prof. P. Boesze (Hungary), Dr. P. Elsakov (Lithuania), Dr. L. Foretova (Czech Republic), Prof. J. Gardovskis (Latvia), Prof. N. Haites (United Kingdom), Dr. G. Moeslein (Germany), Prof. H. Neumann (Germany), Prof. B. Ponder (United Kingdom), Prof. H. Sobol (France), Dr. H. Vasen (Netherlands), Dr. W. Weber (Switzerland), J.-P. Mecklin (Finland – subcontractor).

The scientific objectives of the project included:

1. Elaboration of standards for a model cancer family syndrome (CFS) registries in Eastern Europe
2. Registration of 2000 families with different types of CFS in populations of East European countries (Czech Republic, Hungary, Latvia, Lithuania, Poland)
3. Initiation of European collaborative studies with the use of material collected by East European CFS registries

Results:

Ad 1.

Ad 2. Registered families

CFS type	Country					Total
	Czech Republic	Hungary	Latvia	Lithuania	Poland	
Breast/ovarian cancers	140	32	2	44	720	938
HNPCC	54	12	57	13	291	427
Other or undefined CFS	66	22	1	3	2199	2291
Total	**260**	**66**	**60**	**60**	**3210**	**3656**

Ad 3. 22 collaborative studies have been performed or planned.