Vol.7 n1

Periodico Trimestrale di Ricerca e VRQ in Medicina Generale fondato nel 1996 Da S.I.V.R.Q. (area Cure Primarie) e SIMG sezione di Verona.
***Comitato di redazione**: Mario Baruchello, Alessandro Battaggia, Enzo Brizio, Attilio Dalla Via, Franco Del Zotti, Bruno Franco Novelletto, Daniele Giraldi, Sandro Girotto, Giobatta Gottardi, Marco Pietro Mazzi, Roberto Mora, Nicolò Seminara, Michele Valente*

La Qualità e le Qualità in Medicina Generale

Anno VII n.1 - Marzo 2002
Iscrizione Tribunale di Verona n. 1187 del 12/12/95

***Proprietario ed Editore**: Associazione Qualità Medica*
***Direttore Responsabile**: Roberto Mora*
***Collaboratori Internazionali**: Julian Tudor Hart, Paul Wallace*
***Proprietario**: Associazione QM*
***Direzione**: Via dell'Artigliere, 16 – Legnago (VR)*
***Redazione**: c/o Ordine dei Medici di Vicenza, Via Paolo Lioy, 13 - 36100 Vicenza*
***e-mail**: mario.baruchello@tin.it - delzotti@libero.it*

Editorial

RESEARCH AND PROFESSIONAL PROSPECTIVES

Mario Baruchello

The Law Decrees of 1999 and May 2001 regarding experiments in territorial medicine made research break into our profession even more officially.
Clinical and pharmacological research is an important moment for the cultural area of General Practice, and this is a fundamental phase in which you can rise General Practice to the dignity of a scientific discipline also in Italy. Other criteria that must be respected are the following :

- Have an order field .
- Have a coded body of knowledges
- Have a scrupulous training ground

A thorough vision of the whole, with important initiatives in all fields, was brought about during these years with perseverance by groups of GP's belonging to the Italian General Practice who were connected to the international scientific debate. Yet other actors in this scenario have not done and are not doing their part in order to carry out the deep change which is necessary for a genuine renaissance of family practice.
The top management of scientific societies have not overcome the provincial and personalistic logics of the medical culture at all times and still today they still have not found a common approach which is present among their associates: Universities cherish more political interests and it will be a problem if they do not sense areas that can be colonized or if they do not give access to new integrated departments together with the territorial institutions; the regional and central administrative authorities have never created efficient structures able to guarantee continuity and development for a well-organized system of public health. Research in the pharmacological field that is opened today to the single GPs in MMG can outline the the great optimism in the future scenarios.
In an area having low turnovers, protected by titanic corporative barriers which tend to defend substantial income positions, many young colleagues who have attended with an unbound attitude regional professional training schools, joined us.
Researchers that will cluster together with pharmacological industries will be the first who will have to certify structural standards, procedures and results in a innovative turn that will break down the isolation of " practice only ". These researchers will have to share and put into the network (and our model of Netaudit is an forerunner example in this field) training, activities and evaluation, common grounds with other colleagues that will constitute a hauling cultural force.
These colleagues want that their quality be acknowledged in a general re-evaluation of the personal curriculum in order to constitute a true economical and carrier class structure, within the profession and in training. We are certain that, ever since we have the force of true research, which is important in the opinion of every enthusiast supporter of General Practice, the field of interest will greatly expand way past the bonds we have with industry.
I think that in the next future, we will assist to a great development of a rigorous scientific method applied to:

- single pathologies with a tracing value
- organizational models with a macro and micro managerial/entrepreneurial development
- welfare grounds
- guidelines
- specific epidemiological problems regarding population clusters assisted by GPs.

Saturday 20 April 2002 in Parma during the Meeting "La ricerca in medicina generale in Italia e in Europa " all Italian colleagues will be able to compare their experiences in this type of action, going from clinical audit to pharmacological trials. Beside the famous fathers of European research such as Frank Dobbs and Richard Grol, Franco Del Zotti will also present Netaudit experiences and a session containing original Italian studies, which will be evaluated by an International Scientific Committee. Participation is open to all. For ulterior information please contact:
Claudio Carosino (carosino@symbolic.it)
Paolo Schianchi (paolo.schianchi@millenet.it)

RESEARCH

EXPERIENCE WITH A METHOD FOR RESEARCH AND CONTINUOUS MEDICAL EDUCATION

Pio Pavone, Anna K. Rieve, Giancarlo D'Innocente, Giuliano Salvio, Aristide Di Fulvio (Abruzzo)

PREMISE

Since 1998, in the Abruzzi obligatory continuous medical education for General Practitioners is implemented yearly with eight courses on different subjects, lasting four hours each. Participants are subdivided into groups of approximately thirty General Practitioners for each course.
The high participation rate among General Practioners provides a precious opportunity to evaluate their mode of working in the different local contexts.

RATIONALE

Data collection in General Practice is fundamental in primary care quality assessment. The more wide and unselective the participation of General Practitioners is, the more faithfully the obtained data reflect reality.
The use of multiple-choice questionnaires at the admittance to the course is a simple investigation mehod, which is easy to elaborate and allows evaluation already during the same course in order to adjust the educational process to he real needs of the participants.

PURPOSE

We want to suggest the inquiry described below as a methodological model both for research on primary care quality and for the continuous medical education process of General Practitioners.

METHOD

At the onset of the formation course on the subject "Palliative care in General Practice" 288 General Practitioners (GP) received a questionnaire titled "Inquiry on pain therapy for cancer patients in General Practice" (fig.1) consisting in a single A4 size sheet displaying twenty questions and multiple-choice answers predisposed for easy transcription and elaboration on an electronic calculus sheet or on a similar papery grate. Training animators invited and instructed GPs to fill out the questionnaires before the start of didactic activity. During the course, one of the two animators immediately elaborated collected questionnaires, and the data thus obtained were discussed while carrying out the same course.
In detail, elaboration proceeded as follows:

- The twenty questions were reported sequentially in in the first column of the calculus sheet
- The answers or the indication "no answer" (NA) were reported on the second column
- The subsequent columns showed the global number of filled out questionnaires and the respective answers for each following course
- After conclusion of the whole series of courses on the same subject, results were assembled on one table, added and graphically visualized (fig. 2)

RESULTS AND CONCLUSIONS

1. The rate of participation to the research was satisfying: 155 of the 288 questionnaires handed out were compiled and returned.
2. The degree of completeness in compilation was good: an answer was given to 88% of the questions.
3. As seen in the figure, data evidence on one hand a clear divarication between sensitivity and willingness of GP towards pain of his patients, on the other the skill to plan a coordinate series of individualized steps.
4. This method, subsequently also applied to other subjects in obligatory continuous medical education, proved to be:
   - practical due to feasibility, elaboration simplicity, swiftness and easy visualization of the data
   - sensible in graduating performance levels of GPs
   - relevant in highlighting qualitative deficits in primary care as compared with standards and, consequently, pointing out educational needs
   - reproducible in different contexts of continuous medical education and applicable to different clinical management problems in primary care.
5. The quality of data obtained with this method is comparable with those from literature, and the results are similar, but local data collection may represent a particularly useful contribution to:
   - rationalizing resources allocation
   - integrated management of clinical problems
   - performance status comparison among GPs and self-audit
   - outcome evaluation of the educational process.

To allow GPs to investigate and to think over their own way of working in the light of updated knowledge may thus represent a powerful stimulus towards professional improvement and it may change research into a truly formative process.

BIBLIOGRAPHY

G.Ventriglia - Dilani: "La ricerca clinica epidemiologica in MG" pag 651-663 Il Medico di MG Vademecum 1999 - Hippocrates - Milano

Fig 1

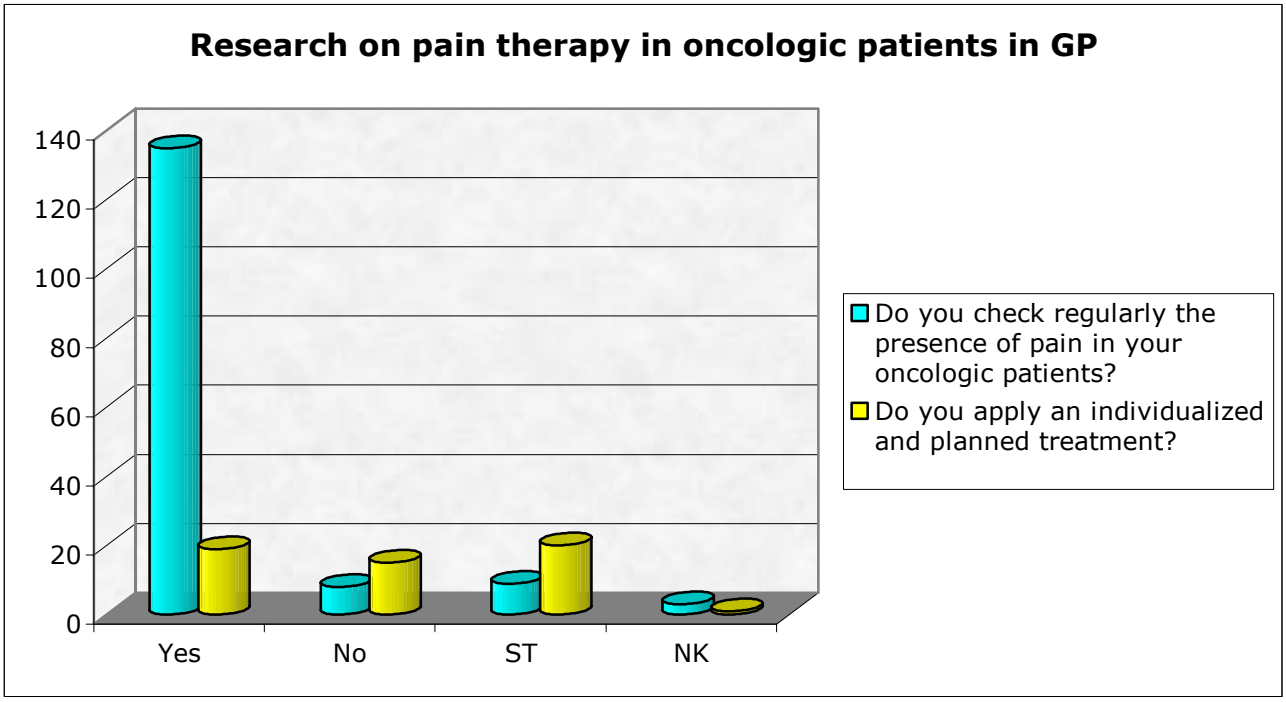
Questionnaire on pain therapy in oncologic patients in GP

Date _____ N° __

You can answer Y - N - ST (sometimes) - NK (not known) to these questions:

1	Do you check regularly the presence of pain in oncologic patients?	Y	N	ST
2	Do you apply an individualized and planned treatment?	Y	N	ST
3	Do you train patient and relatives to self-management, if possible?	Y	N	ST
4	Do you assess the state by analgesic scores?	Y	N	ST
	When do you begin a pain therapy?			
5	If patient is suffering many hours in a day?	Y	N	ST
6	If patient tries to resist the pain as possible?	Y	N	ST
7	If patient uses drugs when pain get unbearable?	Y	N	ST
8	If patient doesn't wish to see other people because of pain?	Y	N	ST
9	If patient wakes up by night because of pain?	Y	N	ST
10	Do you send patients to Hospital because of severe pain?	Y	N	ST
11	Do you know a Paint Therapy Center in your ASL?	Y	N	NK
12	If "Y", do you send them your patients? Had you some consultation?	Y	N	ST
13	Every year how many patients with severe pain do you have they don't respond to common therapy? (A: less than 3 - B: 3 - 6 C: more than 6)			
14	Do you prescribe weak opioids?	Y	N	ST
15	Do you prescribe strong opioids?	Y	N	ST
16	If "N" why don't you prescribe opioids? A: poor experience B: fear C: too many bonds for prescription D: others			
17	Do you have the opioids book of prescriptions?	Y	N	
18	Which is the best place to care patients with cancer and pain? A: Hospital B: House C: Hospice			
19	Did public structures satisfy your needs about oncologic patients with severe pains?	Y	N	ST
20	Do you know if these 10 drugs have now a different modality of prescription? Buprenorphine, Codeine, Dehydrocodeine, Fentanyl, Idrocodone, Metadone, Morphine, Oxycodone, Oxymorphone	Y	N	NK

Fig 2



RESEARCH

Counselling for physical activity (assessment and counselling for patient-oriented exercise), on life and quality style of fat patients in primary care

Massimo Bolognesi - MMG - Cesena

Abstract

Introduction: The civilised and industrialised nations face two major "epidemics" concerning two highly related life-styles: obesity and physical inactivity. There are numerous interactions between physical activity and obesity: increasing one's physical activity may reduce the risks connected with obesity, favourably distribute the body weight, and provide a wide range of positive effects related to psychological and physical health, even when no weight loss occurs. One of the main objectives of the Italian National Health Intervention is the individual promotion of healthy life-styles and behaviours, and to maintain health habits. An ideal context for health promotion and preventive medicine seems to be the "setting" of the primary care provided by the general practitioner (GP). Since people trust the GP, s/he plays an effective and important role in behaviour change.

Purpose: The aim of this study was, therefore, to evaluate of the impact of GPs' counselling on cognitive, behavioural and quality of life indicators in overweight and obese patients. This was done through Prochaska and Di Clemente's transtheoretical model (1986) applied to physical exercise via a specific program, which Patrick, Sallis and Calfas called "Patient-centered Assessment and Counseling for Exercise" (PACE, 1999).

Materials and Methods: Individuals were randomly selected during routine visits at the physician and were randomly split into an experimental (n=48) and a control (n=48) group. Body mass index (BMI) and abdominal girth were assessed as objective biometrical parameters. Patients self-reported their self-efficacy, readiness for physical activity, and quality of life.

Results and Discussion: There was a significatly lower in BMI ($p<0.05$) and abdominal girth ($p<0.05$) in the experimental group compared to the control group after a 5-6 month follow-up. Within the experimental group self-efficacy and stage of physical activity increased ($p<0.05$). Moreover, a general improvement in the physical and mental components of quality of life within the experimental group was highlighted. This indicated that the GPs' counselling was effective. The present study contributes to the growing evidence supporting the employment of the transtheoretical model which, when carefully delivered thorugh a protocol such as PACE, becomes a very useful method to help understand how and why an individual adopts physical activity.

Discussion

The present study examined the GPs' counselling impact on physical activity in a sample of obese and overweight patients by means of the PACE program (Long, et al. 1996; Patrick, 1994). It is important to understand the role and the effectiveness of the GPs' intervention in health promotion and to change patients' behaviour. Clinical prevention represents a link between public health and primary care: the GPs' capacity to provide suggestions aimed at the promotion of health is a potentially important primary care instrument which, however, is rarely employed.

Since the majority of the Italian population, just like most individuals in other technologically advanced nations, is made up of sedentary people or by individuals who are scarcely active, it is necessary to resort to effective interventions, in order to spur the individuals – especially those affected by obesity and overweight – to adopt regular physical activity. However, there are many individual and social barriers explaining the problems of adopting and subsequent maintenance of physical exercise. Among the individual barriers are; the difficulty to apply the counselling in different contexts; the lack of cultural readiness for the counselling due to the existence of a technological and impersonal medical science. Some social reasons include: general lack of sports and health culture, lack of exercise norms, and lack of infrastructures for the performance of outdoor activities.

To overcome some of these barriers within this investigation, the experimental group received 5-6 months of short motivational counselling by means of the PACE protocol. Such protocol derives from Prochaska's transtheoretical model (1986) and was applied to the adoption and maintenance of physical activity while aiming at highlighting significant changes in the objective and subjective parameters. After analysing the present sample, it was found that the counselling had a significant impact on biometrical objective parameters (BMI and abdominal girth), and subjective parameters (physical component of quality of life, stage of physical activity, and self-efficacy). The BMI and abdominal girth decrease and the increase of physical exercise and self-efficacy obtained through the GPs' counselling may play an important role for diminishing the risks of contracting severe diseases that might affect mortality/morbidity (for instance, cardiac diseases and metabolic diseases (diabetes), Brancati et al., 1999; Lee et al., 1998; Oster et al., 1999). The results also support other findings, which indicate that the benefits obtained from regular exercise can be referred not only to the reduction and maintenance of body weight, but also to mortality decrease in obese and overweight people compared to people of average weight who lead a sedentary life (Blair, 1999; Blair et al. 1989; Fontaine et al. 1996; Higgins et al. 1993).

The analysis of the physical (PCS) and mental (MCS) quality of life components of the SF-36 showed that the experimental group tended towards a general physical improvement. The results of the present study seem to

confirm what Doll et al. had previously stated (2000); that bad health conditions in obese subjects were mainly due to the physical component, sharing Palinkas' theory (1996) about the relational unpredictability between BMI and SF-36 mental component.

The gender specific analyses lead to the conclusion that female patients do not seem to be influenced to the same extent as male patients by the physical activity counselling. Firstly, fewer women were recruited to the experimental group (43,8%); secondly, they all were between 40 and 60 years old and almost all have them were married and had children. Due to these demographics and cultural reasons (deeply rooted life-styles and family situations), women may find it more difficult to combine their house-works and job tasks with the adoption of physical activity that might help them achieve a cognitive-behavioural change with respect to their life-style. As a consequence, the female portion of the population was more likely to be affected by sedentary habits and overweight as women sometimes lack cultural and economic means. Further, they usually have fatalistic attitudes whenever they deal with health problems and health management (Bosio, 1999). Male patients, on the contrary, besides being prevalent in the experimental group, probably managed to combine the adoption of physical activity with their social and professional tasks, thus obtaining a higher reinforcement on their own capability to keep on exercising.

The study has also highlighted the utility of the PACE protocol (Calfas et al., 1996) helping GPs overcome the barriers that prevent them from offering adequate advice. PACE is helpful since it reduces the duration of intervention while improving the GPs' knowledge and abilities. Several issues, representing GPs situations, which this study had to overcome, were: lack of motivation (due to the lack of reimbursements) and little time available for the optimisation of the GPs' counselling (the GP is usually heavily burdened with bureaucratic tasks that prevent recurring contacts with patients in order to provide an adequate follow-up). Moreover, an effective, recurrent counselling activity aimed at promoting the adoption of physical activity must also be provided with specific, detailed information on physical activity. This is even more necessary if the counsellor is indifferent, doesn't regularly exercise and doesn't believe in the possibility to be gratified with a counselling activity.

At the end of this project, the majority of the participating GPs changed their attitudes and practical behaviours with respect to exercise, indicating that they will be more ready to apply the counselling to obese patients and track the objective and subjective parameters regularly. Three of the eight doctors involved adopted regular activity, indirectly benefiting from the counselling.

The predicted success of the physical activity counselling was most likely due to the recruitment of one single group – subjects in the stages of preparation and contemplation (not active but ready). These stages seem to be most affected by the counselling intervention – since these individuals increased their self-efficacy. As far as this aspect is concerned, previous studies too had found that self-efficacy was the most strongly correlated factor (Sallis, et al., 1989) and that it was a strong predictor of physical activity adoption (Sallis et al., 1996; Sallis, Hovell & Hofstetter, 1992).

The present study adds to the literature and the growing evidence supporting the employment of the transtheoretical model which, when carefully matched to a specific protocol such as PACE, becomes a very useful tool that helps understand how and why an individual starts a physical activity. It is worth noting that the present research employed subjective and objective measures, thus avoiding the limitation of many other studies, which employed the transtheoretical model through the analysis of self-reported data only.

The use of specific intervention strategies for each stage is recommended as this facilitates the progressing from the adoption of physical activity to the stage of maintenance (Marcus, Banspach et al., 1992). One of the main implications of these findings is that it is counterproductive to consider the individuals who do not exercise as a homogeneous group, both in the research domain and within the clinical interventions. As DiClemente et al. pointed out (1991), researchers in the clinical and social sectors may benefit from further analysis of the differences within the stage whenever they have to devise and test interventions.

In conclusion, the present study is in accordance with the other studies, since they showed that it is possible to obtain a meaningful classification of the general population by means of a self-assessment method for the regular exercise stage. It also corroborates the theory of the usefulness and importance of a short motivational exercise counselling intervention concerning people's health and quality of life within a context of public health prevention. The study of the individuals' characteristics through the assessment of their motivational readiness is an important step forward for the development of health promotion strategies, which may be applied to large segments of the population.

Bibliography: Prochaska, J., Di Clemente, C. (1986).”Toward a comprehensive model of change”. In W. Miller & N. Heather (Eds), Treating Addictive Behaviours, London, Plenum.

Prochaska, J.O., Marcus, B.H. (1994). “The transtheoretical model: Application to exercise”. In: Dishman RK, ed. Advances in exercise adherence. Champaign, III.: Human Kinetics; 161-80

PACE Research and Development Team, (1999).” Patient-centered Assessment and counselling for exercise and Nutrition”. San Diego State University Foundation and San Diego Center for Health Intervention

Ministero della Sanità (1998). Piano Sanitario Nazionale 1998-2000, Roma, Ministero della Sanità

Apolone, G., Mosconi, P. (1998). “The Italian SF-36 Health Survey: translation, validation and norming”. *J Clin Epidemiol*; 51:11,1025-36

META-ANALYSIS

Evaluation of the effectiveness and safety of Tamoxifen in primary prevention of Breast Cancer and efficacy in clinical practice.

Dr. Clementino Stefanetti - MMG - Casorezzo (MI)
stefanetti@libero.it

Research Strategy:
I searched for the following "medical subject headings": "breast neoplasms/prevention and control" in Medline AND "chemoprevention" AND "Tamoxifen" AND "Clinical trials".

Selection Criteria:
Only controlled studies and doubleblind studies between Tamoxifen versus placebo.

Description of the Studies:
Three trials, which appeared to satisfy the selection criteria were included with 21267 participating women.

			Invasive cancer for 1000 women-year		
	N. of women recruited	N. of breast cancers *	Tamoxifen	Placebo	Relative Risk (95% CI)
Trial					
NSABP P-1 HRT not allowed Calculated risk accordino to the Gail model HRT not allowed	13 388	368	3.4	6.8	0.51 (0.39–0.66)
Italian Tamoxifen Prevention Study HRT allowed Increased risk not required Ovariectomy in 48% Hysterectomy in 98.3%	5 408	41	2.1	2.3	0.92 (NA)
Royal Marsden Hospital Tamoxifen Randomised Chemoprevention Trial Rischio accordino hereditarness HRT in 26%	2 471	70	4.7	5.0	0.94 (0.7–1.7)

One trial comprised 13388 women in an over 35 years age group having an increased breast cancer risk, a medical history with a lobular cancer in situ (LCIS) or a 5-year Gail-index risk superior to 1.66%. This index is calculated by considering age, menarche age, the number of breast biopsies, hereditariness for breast cancer, age of the first birth delivery and ethnic group. There also is a software which is able to calculate personal risk and can be downloaded at the following URL:
http://oncolink.upenn.edu/disease/breast/cause/breastca_risk

In this study Tamoxifen was given in doses of 20 mg/die for 5 years and the average follow-up period was of 47.7 months. 124 breast cancers were registered among the 6681 treated patients and 244 between the 6707 controls, thus showing a reduction of 49% ($p < 0.00001$) of the risk. The average risk of the participants was of 3.2%. The dropouts were 21.6% among the treated patients and 19.7% among the controls. No estrogenic and progestinic therapy was allowed. In a second study carried out in Italy with 5408 recruited women having and average age of 51 years and for an average follow-up period of 46 months, Tamoxifen was given at the doses of 20 mg/die for 5 years. All participants could use a estrogenic and progestinic birth control pills. No risk increase was requested. The dropouts were 27.8% in the Tamoxifen group and 24.7% in the control group, 48% of the women had undergone ovarectomies and almost 98.3% had undergone hysterectomies. 19 cases of cancer were found among the 2700 treated women and 22 among the 2708 control group ($p < 0.64$). In the English study, 2471 women having an average age of 47 years were recruited and also in this case, Tamoxifen was given in doses of 20 mg/die for an average follow-up period of 70 months. 34 cancers were found among the 1238 treated patients and 36 among the 1233 controls. The estrogenic and progestinic therapy was already present in 26% of the women. The dropouts were 26% among the treated patients and 14% among the controls.

NSABP = National Surgical Adjuvant Breast and Bowel Project
CI = Confidence interval
NA = not available.
HRT = substitutive hormonal therapy
Includes invasive and non-invasive cancers

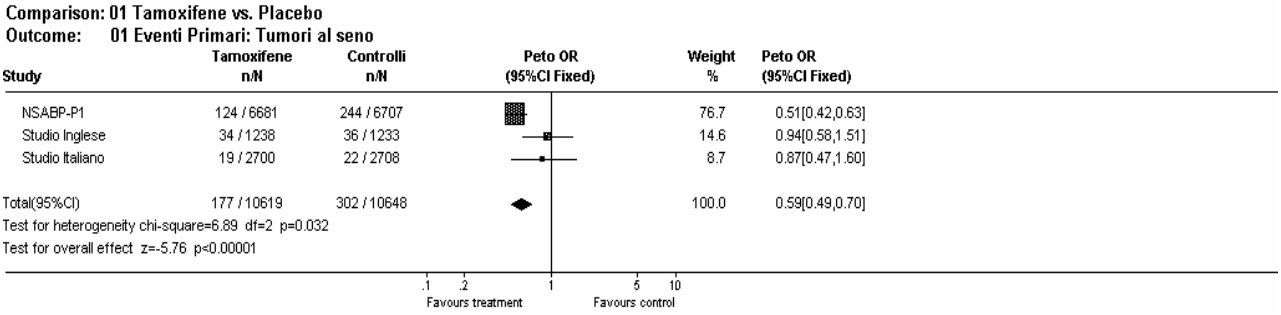
Adverse Events:

Adverse events reported in the NSABP P-1 trial study			
	N. of women		
Events	**Tamoxifen**	**Placebo**	**Relative Risk (and 95% CI)**
Endometrial cancer			
All ages	**36**	**15**	2.53 (1.35–4.97)
> 50 years	27	7	4.01 (1.70–10.90)
Stroke			
All ages	**38**	**24**	1.59 (0.93–2.77)
> 50 years	35	20	1.75 (0.98–3.20)
Venous Thrombosis Prof.			
All ages	**35**	**22**	1.60 (0.91–2.86)
> 50 yr	24	14	1.71 (0.83–3.58)
Pulmonary Embolism			
All ages	**18**	**6**	3.01 (1.15–9.27)
> 50 yr	16	5	3.19 (1.12–11.15)
Cataract	**574**	**507**	1.14 (1.01–1.29)

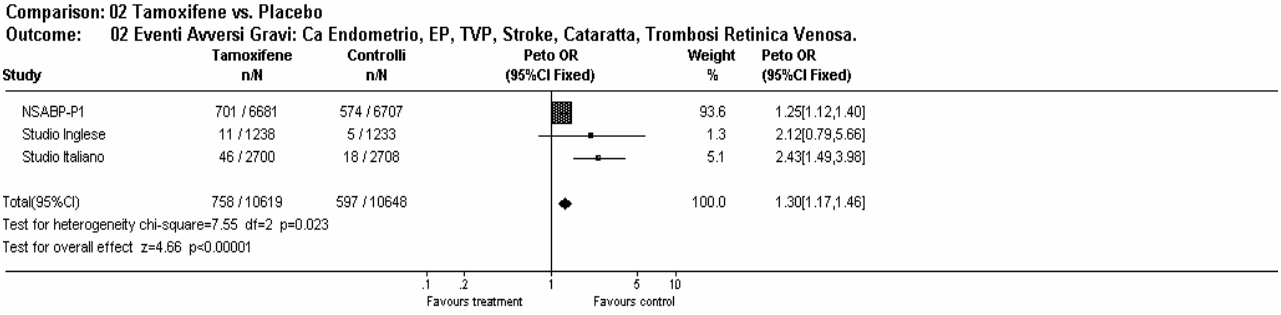
English Study			**Italian Study**			
	Tamoxifen	Placebo		Tamoxifen	Placebo	Total
			Superficial Phlebitis	33§	9	42
Other Cancers	19	24	**Deep Venous Thrombosis**	6	3	9
Endometrium	4	1	**Other Thrombosis**	4*	3	7
Ovary	2	5	**Pulmonary Embolism**	1^	1	2
Gastrointestinal	3	3	**Post-phlebitis syndrome**	0	1	1
Others	10	15	**Venous Thrombosis of the retina**	1	0	1
Venous Thrombosis Prof.	4	2	**Others**	1	1	2
Pulmonary Embolism	3	2	**Total**	46	18	64#
Deaths						
Breast Cancer	4	1				
Other Causes	5	5				

Data regarding serious adverse events of which some regard the same women.
§ 33 events in 27 women.
*A patient had also a superficial phlebitis
^a patient had also a superficial phlebitis
64 events in 56 patients

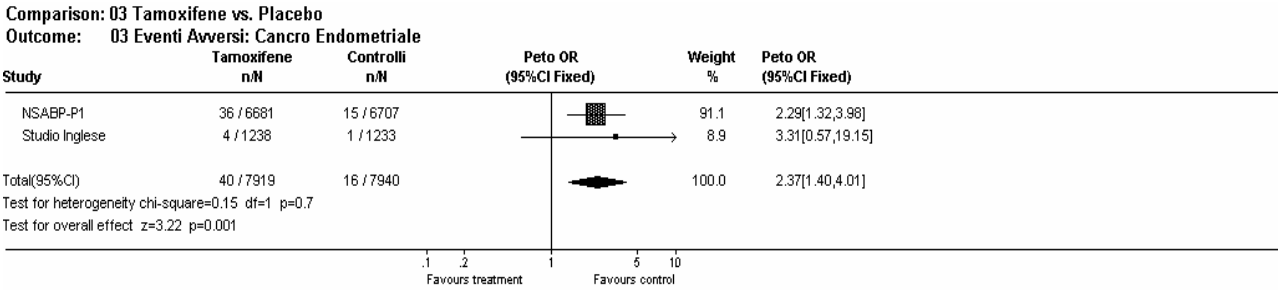
Data Analysis:
We shall now analysis the overall statistics regarding breast cancer prevention that emerges from the 3 studies:
177 events among the 10619 treated patients and 302 events among the 10648 controls. With these data we can calculate:
RR (Relative Risk) = 0,59 (0,49 to 0,71)
RRR (Reduction of the Relative Risk) = 0,41 (0,29 to 0,51)
ARR (Reduction of the Absolute Risk) = 0,011694 (0,007737 to 0,015733)
NNT (Necessary Number that should be treated) = 86 (64 to 130)
If we represent the numbers in a graphical layout, as we are used to see with all Cochrane's meta-analyses, we will obtain the following graphic:



You can clearly notice the significative differences in the totals statistics, represented by the rhomb. We must treat 86 women to prevent a breast cancer.
Let's now analyse the data we have on the side effects. There were 758 adverse events among 10619 treated patients and 597 among 10648 controls, which give:
ARI (Increase of the absolute risk) = 0,015315 (0,0219 to 0,00876)
NNH (Necessary number to cause Damage) = 65 (45 to 114)
We will represent the numbers on the usual graphic therefore obtaining:



Even here we notice the significative differences in the statistics on the rhomb.
If we analyse in the adverse events, the only endometrial cancers (excluding the Italian study because the women had underwent hysterectomies) we obtain the following results:
40 events among the 7919 treated patients and 16 events among the 7940 controls, which give:
ARI (Increase of the absolute risk) = 0,002264 (0,003755 to 0,000919)
NNH (Necessary number to cause Damage) = 329 (198 to 811)
We now will represent the data on the usual solid graphical layout, which also in this case is statistically significative



If we then analyse the data by risk area, which can be obtained by the NSABP-P1 study, we can obtain the following data:

	N. of infiltrating cancers		N. of women			
	Placebo	Tamoxifen	Placebo	Tamoxifen	**RRR**	**NNT**
Predictive Risk at 5 years, %						
≤ 2.00	35	13	1660	1636	**0,62** (0,298 a 0,798)	**77** (46 a 194)
2.01–3.00	42	29	2031	2057	**0,32** (-0,085 a 0,572)	**152** (67 a infinito)
3.01–5.00	43	27	1791	1714	**0,34** (-0,052 a 0,591)	**122** (57 a infinito)
≥ 5.01	55	20	1117	1169	**0,65** (0.43-0.79)	**32** (21 a 56)

Discussion:
In secondary prevention, a meta-analysis of 55 RCT with 37.000 treated women for breast cancer with Tamoxifen for a maximum period of 5 years and a follow-up period of over 10 years cured by the Early Breast Cancer Trialists Collaborative Group (Lancet 1998 351: 1451-67), set up some points. Out of the 8.000 women with ER- receptors, Tamoxifen had had little effects. In the 18.000 women with ER+ the use of Tamoxifen for 1, 2 or 5 years, determined a reduction of the local relapse in respectively 21%, 29% and 47% of the cases. The incidence reduction of the contralateral breast cancer was of 13%, 26% and 47% and the reduction of the death rate was of 12%, 17% and 26% in a 10-year follow-up period. The relative NNT is:

Tamoxifen in breast cancer in a premature phase		
Results	**Years of Tamoxifen**	NNT (95%CI)
Relapse Prevention	1	18 (13 a 30)
	2	16 (13 a 26)
	5	8 (7 a 10)
Prevented deaths	1	28 (18 a 66)
	2	30 (21 a 49)
	5	22 (15 a 36)
Endometrial cancer	5	NNH 97 (68 a 168)

The incidence of endometrial cancer was higher with Tamoxifen and it was statistically significative. In absolute terms it was approximately half of the number of prevented contralateral breast cancers. The three studies regarding primary prevention still present dark sides. As we have seen in the 2 European studies it has been shown that Tamoxifen does not prevent in a significative manner breast cancer differently from what was shown by the American study in which there was a significant statistical difference. Some explanations were given for these differences, and they are convincing. It is true that the European studies were smaller, but the had the power necessary to demonstrate the small differences.

A possible explanation is the age difference of the women in the studies. The English study had younger women (47 years) respect to the women in the American study having a effectively positive hereditariness and maybe these women were less susceptible to prevention. Besides, they were followed for a longer period of time Than the women included in the American study. There is data on animals that demonstrate the annulment of the protective factor belonging to Tamoxifen and therefore a longer follow-up would be necessary to notice this type of phenomenon. The Italian study can stand alone since all women had undergone hysterectomy, and half of them had undergone An ovarectomy, which alone has a protective effect on breast cancer and in addition, there were many more dropouts (26%).

Without doubt, the weakest aspect missing in all these studies, is the fact that there is no data on death prevention which would have surely shown with a longer follow-up period.

Implications for clinical practice:
In 1999, the American Society of Clinical Oncology re-examined the use of Tamoxifen and of Raloxifen for the reduction of the risk of Breast cancer (NEJM, 343, 191-8, 2000). The report recommended women with an increased risk (defining as a risk at least 1.7% for 5 years) to get a prescription of Tamoxifen at a dose of 20 mg/die for 5 years after an appropriate counselling together with the woman, in which she would be informed regarding risks and benefits and where the final decision would depend on the woman's personal perceptions of the risk she was running and on her personal reaction to the risk. Also the American College of Obstetricians and Gynaecologists *(ACOG Today* 1999; 43(9): 224) agreed on this last point. The identification of the candidate for a therapy with Tamoxifen requires an evaluation of the risk by means of an appropriate software or tables. There are 4 models to calculate this risk, two of the most famous are the Gail and Claus models, and the tables are herein exposed. Raloxifen is suggested at the moment only for the prevention and treatment of post-menopause osteoporosis and not for breast cancer.
My personal opinion is that the data that emerges from the 3 studies shows great potentials, but it still attend confirmation with longer follow-up periods, hoping that data regarding death prevention will be available. Now arriving is a study, which compares Tamoxifen and Raloxifen.

An alternative approach consists in the calculation of the risk Factor, and if it is superior to 2%, suggest a yearly mammography together with self-palpation. The inconsistency of a mammographic screening in women between 40-49 years of age because of a major density of the breast is clear to all, also because of the many false positive examinations and the rareness of cancer in this age which annul the benefits tied to screening. For those women with an increased risk, determined by means of the above-mentioned methods, there should be a program of annual screening with careful balancing between risks, benefits and costs. In a study (Positive predictive value of screening mammography by age and family history of breast cancer. JAMA 1993; 270: 2444) regarding women between 40-49 years, an abnormal mammography had a three times greater probability to discover a cancer in those women having hereditariness for breast cancer than in women with no hereditariness.

Bibliography:
1. Early Breast Cancer Trialists' Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomised trials. Lancet 1998; 351: 1451
2. T. Powles, R. Eeles, S. Ashley et al. Interim analysis of the incidence of breast cancer in the Royal Marsden

Hospital tamoxifen randomised chemoprevention trial. Lancet 1998; 352: 98
3. U. Veronesi, P. Maisonneuve, A. Costa et al. Prevention of breast cancer with tamoxifen: preliminary findings from the Italian randomised trial among hysterectomised women. Lancet 1998; 352: 93
4. Fisher B., Costantino J.P., Wickerham D.L., Redmond C.K., Kavanah M., Cronin W.M., et al. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. J Natl Cancer Inst 1998; 90: 1371
5. Armstrong K., Eisen A., Weber B. Assessing the risk of breast cancer. NEJ M 2000; 342: 564
6. Chlebowski R.T. Reducing the risk of breast cancer. NEJM 2000; 343: 191

AUDIT

THE OTHER SIDE OF BLOOD PRESSURE IN GENERAL PRACTICE

Franco Del Zotti M.D., Marco Grassi M.D., Alessandro Bussotti M.D., Tiziana Murari M.D., Carlo Pizzillo M.D.

Key words: Blood Pressure, Arm, Quality control

BACKGROUND

A Blood Pressure (BP) examination is one of the most frequent measurements performed in General Practice, but few studies tell us how to increase the quality of measurement. We coordinated an abbreviated Audit to evaluate on BP factor: the measurement of BP in both arms.

OBJECTIVES

a) Demonstrate that it is possible to increase the rate of an "at least once" BP measurement in both arms, using an abbreviated Audit and a visual reminder (a label on the sphygmomanometer).
b) Examine how many patients have an "interarm" asymmetry (> 10mm Hg).

METHOD

5 GPs decided to by-pass the baselines of Audit: they started the study by declaring that they had "never or hardly ever" recorded the BP value in both the right and left arm. Therefore, for an overall period of two months, and in patients over the age 18 coming into to the office for check-ups, they decided to increase this very low rate of BP recording by utilizing a visual reminder such as a colored label on the sphygmomanometer.

RESULTS

The interarm difference In 184 (34%) patients an appreciable difference (>10 mm Hg) was noticed, with a predominant difference of 60% in the right arm (112/184; $p<0.01$).).

Frequency of measurement. The "interarm BP" was examined in 535 patients (total number of patients of the 5 GPs was = 7944). So, for two months we included a percentage of 6.7% patients; following this rhythm we can estimate to include 40% of the total patients on an annual basis.

Conclusions

A) An interarm BP difference is considerably frequent (34%).
B) We found that the triad baseline agreement (that takes into consideration the missing measurement) + the simple visual reminder + temporal feedback in few months (two months) is most advantageous to increase the rate of a test that should be performed at least once according to the "interarm BP measurement" method.

BACKGROUND

International guidelines concerning the diagnosis, the assessment and the treatment of hypertension encourage the measurement of interarm BP in patients with ischemic disease [1,2], but few studies were conducted in this field. During a study conducted in the United States with an equivalent number of patients (610), but with different settings (hospital patients), 53% of the patients presented a diastolic and systolic blood pressure that differed on respect to another by > 10 mm Hg. 19% of these patients presented a systolic and diastolic BP having a > 20 mm Hg difference [3]. Other studies had either few patients or regarded only patients with vascular disease [4,5]. Therefore, our study aims to analyze the frequency of asymmetries in the usual setting of the Family Doctor's office.

THE RESEARCH

To determine the normal difference in bilateral upper-extremity BP measurements, we conducted a prospective observational study on an available sample of office patients who were visited during a normal general practice office work. This prospective observational study was conducted by 5 general practitioners coming from various Italian regions. The interarm BP measurements were performed in all patients who had never previously taken this type of test before. We considered a significant interarm asymmetry a difference in the BP measurement of over 10 mm Hg (systolic or diastolic or both). All patients who exhibited such asymmetry were registered in an electronic database in order to remember the arm on which we performed the BP measurement during the following visits.

We performed BP measurements for a total 40 working days.
The patients (all over age 18) were selected using the following inclusion criteria:
1. All patients suffering from hypertension
2. All patients who required a clinical consultation (including an objective examination)
3. All patients who requested a BP measurement.

We used a visual reminder (adhesive label applied to the sphygmomanometer) to remember:

1. To perform the interarm BP measurement
2. The inclusion criteria

DATA COLLECTION CRITERIA

All interarm BP measurements and the date in which they were performed were recorded in electronic clinical records. We recorded:

1. The performed interarm BP measurement
2. The arm which presented a higher BP (> 10mm Hg)
3. No differences found in the interarm BP

The software utilized to collect the data allowed to record the data according to these criteria and to the statistical analysis procedures.

THE AUDIT

The GPs decided to by-pass the audit baselines: they started the study after they admitted they had never recorded the BP value in both right and left arm. The absence of the BP data regarding this procedure is directly connected to the use of Clinical Record software which hasn't been projected to contain a standard field in which this type of variable can be registered.

We decided to overcome this absence by utilizing a visual reminder such as a colored label on the sphygmomanometer for a two months period in patients over the age 18 coming into to the office for check-ups.

We used a device (mercury-type sphygmomanometer) with validated accuracy that is properly maintained and calibrated. Patient was seated with the arm at the level of the heart. The bladder size was adjusted for the arm circumference, the cuff deflated at 2 mm/sec and the blood pressure measured to the nearest 2 mm Hg. Diastolic pressure is recorded as disappearance of the sounds (phase V).** We performed BP measurement at each arm chosen first indifferently with a minute interval after the first measurement.

RESULTS

During this two months period (forty days) we examined 535 patients (an average of 107 patients per GP) and recorded their relative BP using the interarm procedure. The five GPs involved in the study assist a total of 7944 patients. The percentage of assisted patients to whom the interarm BP procedure was performed represents a 6.7% of the total population in a period of two months. Following this rhythm we can estimate that we will cover 40% of the entire population on an annual basis. With respect to the total number of BP measurements (in 535 patients), 351 patients presented ≤ 10 mm Hg difference between one arm and another (65.5%), while in 184 patients (34.4%) we noticed a > 10 mm Hg difference while performing an interarm BP measurement.

While searching for arm prevalence in the BP distribution, we found that the right arm had a higher BP in 60.86% of the cases that presented an interarm BP difference: 112 patients had a higher BP in the right arm and 72 in the left one (P<0,01, Exact Clopper-Pearson 95% confidence interval = 53% to 67%). **(see Figure)**

Ultimately, the different interarm BPs were examined in those patients suffering from hypertension, to establish if arm predominance existed. In 55% of the cases the right arm presented the highest BP against 44% in the left arm. In this last case, the difference isn't statistically representative.

DISCUSSION

According to the data analysis, we can assume that in a not small portion of patients that underwent interarm BP measurements, there is a difference (>10 mm Hg) between one arm and another (34%). The arm that presented the most significant differences in the general population was the right one, The frequent presence of asymmetries suggested to perform BP measurements on a routine basis at least once, to be able to detect those patients who have a different BP in the two arms and to establish in which arm it is higher. Furthermore, this double measurement helps to give a definite answer to all those patients who commonly get confused while choosing which arm to stretch out to take a BP measurement.

The second objective of the study, which intended to establish the double BP measurement rate and its increase with time helped by a visual reminder, had positive outcome. According to the data that was recorded during the first two months of the study, we can predict that in a years time it will be possible to extend this double BP measurement procedure in approximately 40% of the patients that are assisted by each single doctor.

Bibliography

1. Chalmers J et al. WHOISH Hypertension Guidelines Committee. 1999 World Health Organization – International Society of Hypertension Guidelines for the Management of Hypertension. *J Hypertens,* 1999, 17:151-185.
2. Joint National Committee. The fifth report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. *Arch. Intern. Med.* 1993; 153:154-183.
3. Singer AJ, Hollander JE – *Arch Intern Med J* 1996 Sep 23; 156(17):2005-8 Blood Pressure. Assessment of interam differences.
4. Fotherby MD, Panayiotou B, Potter JF *Postgrad Med J* 1993 Mar; 69(809): 194-6 Age-related differences in simultaneous interarm blood pressure measurements.
5. Frank SM, Norris EJ, Christopherson R, Beattie C. Anesthesiology 1991 Sep;75(3):457-63 Right- and left-arm blood pressure discrepancies in vascular surgery patients.
6. Ramsay LE, B Williams, GD Johnston, GA MacGregor, L Poston, JF Potter, NR Poulter and G Russell for the British Hypertension Society Guidelines for management of hypertension: report of the third working party of the British

Hypertension Society Journal of Human Hypertension (1999) 13, 569–592

**Ramsay LE, B Williams, GD Johnston, GA MacGregor, L Poston, JF Potter, NR Poulter and G Russell for the British Hypertension Society Guidelines for management of hypertension: report of the third working party of the British Hypertension Society Journal of Human Hypertension (1999) 13, 569–592