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Editorial

Mario Baruchello (mario.baruchello@tin.it)

Julian Tudor Hart: a Friend, a Person, a Quality General Practitioner

Last January 24, 2003 we were honoured to have as our guest for an unforgettable dinner in Verona doctor Julian Tudor Hart.
He has always been a cultural point of reference for our researches and he has always let us cite him as a referee on our publications. His history deserves to be known.
He was born in 1927 in England, he was a student first at Cambridge from 1947 until 1952 and then at the St.George's Hyde Park Corner Hospital in London. He chose to devote his life to take care of the poor coal miners in an isolated and remote area of Wales: he practiced in NHS surgery for over 30 years as a epidemiologist and great clinic, working several time with Archibald Cochrane.
He retired in 1997, and he has been working as a medical-scientific editorialist and writer.
His editorial production consists of more than 120 original pieces focused on General Practice and on the prevention of the cardiovascular diseases. He is a member of the Medical Research Council, an institution famous for his primary care researches.
Great observer both of relationship dynamic and phenomena of the population, he was able to describe the shift of the health demand and the changes of the answers of medicine and of the single physician in the last 50 years.
Some of his works deserve to be quoted: *Coronary Heart Disease Prevention in Primary Care: Seven Lessons from 3 decades* (Fam. Practice, 1990); *Save the General Practice Record* (BMJ, 1989); *What Sort of Letter of Letters do GPS want to receive from Hospital Specialist?* (BMJ, 1989); *Reduction of Blood Cholesterol Levels in the Population: can it be done?* (JR Coll. Gen. Pract., 1986); *Twenty Five Years of Case Finding and Audit in a Socially deprived Community* (BMJ, 1991).

The Medical College of Georgia (USA) has conferred him the prestigious award called "*The Curtis G. Hames Research Award in Family Medicine*" and several other awards. He contributed to give legitimacy and autonomy as scientific discipline to general practice and he represented an example to imitate because of his professional life spent to make life and social conditions of his patients better.
In 1999 The University of Glasgow conferred him the Degree in Medicine *Honoris Causa* for his improvement of quality in general practice through studies conducted such as the one on hypertension.
Politically active he confessed us that he never betrayed his ideals of freedom and that he has also always considered important his patients and the bio psycho and social problems.
Concerning medical education he always stated this: "My medical education began three times. What I learnt at medical school was no use in the hospital. What I learnt in the hospital was no use in general practice".
In the early Seventies, Hart, described the so called "inverse care law" which essentially states "the availability of good medical care tends to vary inversely with the need for it in the population served".

As a conclusion Hart has given us a precious decalogue about guidelines for better communication between caregiver and patient:

1. Make sure you have their attention
2. Speak at eye level and enunciate
3. Use simple, direct statements
4. Ask. Try not to tell
5. Move closer
6. Talk around difficulties and use gestures
7. Talk with, rather than about
8. Listen
9. Give yourself plenty of time
10. Try, try again

No one of all the friends at the restaurant table in Verona will never forget the delicious Risotto with Amarone of that night.

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WHAT'S THE USE OF RESEARCH IN PRIMARY CARE?

Julian Tudor Hart

GPs get involved in research for many different reasons. Equally interesting are the many reasons why most of their colleagues don't wish to get involved. Both groups, researchers and anti-researchers, seem to be prompted by their beliefs in the usefulness (or futility) of research. So this question of use is central.

I am not going to discuss its usefulness to others outside primary care. If University Departments or pharmaceutical companies see value in primary care research to promote either academic knowledge or commercial profit, they may persuade GPs to make their populations available for research, or even to undertake some of it themselves, not because these GPs have been convinced it is useful for more effective practice, but because it will please the university or the company. Many GPs assist such projects even if they think the research is probably trivial or futile, simply because they want to help their university, or get whatever material benefits may come from the companies. Their lack of personal conviction is a major source of poor quality data.

Let us now discuss what really matters, research initiated within primary care because we believe it will be useful to us and to our patients, making our work more effective and our lives easier. Here we can start from an even simpler question: How can primary care for registered populations ever operate effectively or efficiently *without* locally initiated research, at least of an elementary kind? Effective and efficient operation of primary care even as a competitive business requires some local research: Who and where are my competitors? What sorts of car do they drive? Do they attend mass regularly, is this important among the most potentially profitable patients round here, and will it be OK if my wife goes without me? These local questions need local answers. Without them the little business will not succeed. Of course, we are no longer concerned with consumer research of that kind. Our research now concerns intelligent planning of our work so that it is no longer a passive response to consumer demands, with our time shaped by competing wants, but can start to become an intelligent response to needs in our whole registered populations, prioritised to produce optimal health gains rather than to maximise clinical process. To organise our time intelligently we need intelligence, both in its intellectual and its military sense; we need information about our local enemy, ill health, injuries and diseases in the population we serve, and also about our available local allies, the experience and skills of the population itself.

The foundations for effective GP research are laid in the first five years of practice, when GPs are sinking their first roots into the local population, before clinical records and information systems can reach the levels of quality required for published research. In this first stage you aim only to inform yourself and your own team about the general outline, size and shape of what is likely or possible, and the main concerns you and your team share with the local population. This means close attention to every source of local gossip, taking every opportunity to visit people's homes and places of work, with eyes and ears open and, for a while, mouth shut (an aim I personally have never achieved, but I regret that) – so that within five years you have a rounded and almost complete picture of your community, and a realistic understanding of how much you still do not know. After such preparatory work you should have the trust of your population (an asset possessed by hardly any other agency) and a basis for an accurately maintained register of people at risk, a denominator population: not merely the official administrative list for which you are paid, but the real people at risk for your care (whether or not they consult), your *denominator population*.

Serious GP research of any kind depends on *numerators* of health-related qualities, quantities or events defined by replicable criteria, placed over population denominators. Without an accurately maintained denominator population, with names, addresses and telephone numbers maintained and revised weekly by information from all sources – not just by administrative sloths and snails, but by all available local sources of gossip and friendly chat – no worthwhile research in primary care is possible. Worthwhile primary care research does exist in USA, even though it still has no health care system for any whole populations, but only in the few stable islands somehow precariously maintained (usually by university

departments) within the chaos of multiple competing providers, all trying to find the profitable patients and to avoid the unprofitable patients. In Britain and Italy, all GPs start with an immeasurable advantage, that they already have registered lists, and that they still for the most part control access to secondary care, so that they can know what is happening to their patients. These alone are not enough for good research, they must be supplemented by much finer local intelligence, but the basic core of information is already there. With imaginatively selected and rigorously defined numerators, and an accurately maintained population denominator, an immense research output is possible, whose value increases exponentially with time. On the other hand, no amount of statistical sophistication can compensate for an undefined or poorly defined population denominator.

It takes five years to establish a robust denominator, and the popular trust necessary to make intelligent use of whichever numerators you, your team and your population may choose to study. Why do it? Because you, your team, and your patients want their hard work to be effective, less futile than in the past, when we all worked hard, but mostly achieved little in terms of health gain: plenty of clinical process, but little health outcome. Even with relatively small numbers, for common health problems the figures you find will be significant. If they relate to the completeness or effectiveness of clinical processes, they will probably surprise you, or at least they will surprise your team and your patients, all of whom tend to be more optimistic than evidence can justify. Eventually, they may also surprise your local admistrators and elected politicians, who know how rare it is for anyone to base their argument on good local evidence. Locally researched information is an enormously powerful political weapon, above all for getting more and better resources for your team and population. Is this just audit? Yes, but good audit is the beginning of good research.

We GPs have the trust of our populations. We can run up to people's doors, bang twice, shout "Doctor!" as we burst into their homes, and run upstairs to the bedroom to see a sick person, sure that we are welcome and will not be bitten by a dog or reported to the police. Of course, if we choose to sit in our offices believing that home visits are no longer an efficient use of our valuable time, we shall lose this trust, but I assume my readers are not so stupid. We know everybody's name, address and telephone number, whether they are happy in their lives, and whether any of their close family has a life-threatening illness, knowledge we gained in those first five years, and must assiduously maintain thereafter. How many politicians still have such trust or intimate knowledge? Allied with our patients in the shared cause of better health and health services, we are a potentially terrifying political force, particularly if our advocacy is supported by evidence from honest local research.

Research and practice intelligence are not an optional luxury for a few doctors with time to spare, but a necessity for effective and expanding primary care everywhere. This research will be superior to clinical research at any other level, because GPs have a better appreciation of the active and intelligent role played by participants. Just as patients need to become co-producers, not consumers, when they participate in research they should do so as informed people whose intelligence is valued and used. A recent UK study showed that 55% of organisers of double-blind trials took no steps to inform participants of their allocation to treatment or placebo after trials ended, or only told them if they were asked: 40% of these organisers had never even considered the possibility that participants should be so informed, and presumably the other 60% thought it was not necessary[1]. Hospital and university researchers who treat human participants as if they were laboratory rats will have to think again if they want to stay in business.

Hopefully researchers in primary care are well ahead of them. We are in the right place at the right time. The future of most research into human biology lies not in laboratories or hospitals, but in large multicenter studies in the normal human habitat, where people normally live and work: in primary care. Of course, these will have to be initiated at the highest levels of university or national research units, but to maximise their output of useful knowledge they will require intelligent participation by GPs, primary care teams, and patient populations, all with a far more critical and sceptical view of the high echelons of research than trial organisers have experienced in the past. A great deal will depend on pioneers like yourselves.

Julian Tudor Hart

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The importance of home visit

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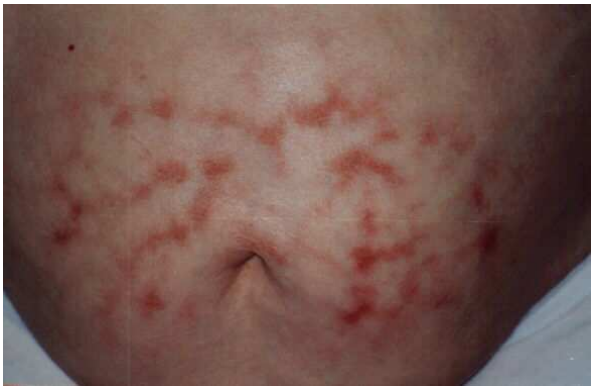
In march 2002, a home nurse of the town I work in, called me because she had noticed on the belly of the madam she used to bath, the presence of something

[1] di Blasi Z, Kaptchuk TJ, Weinman J, Kleijnen J.: Informing participants of allocation to placebo at trial closure: postal survey. *BMJ* 2002; 325: 1329-31

strange. In the afternoon I went and see the problem. What I saw is depict in the picture below. What's your diagnosis ?



Why to see the madam at home was so useful? Because just entered the living room were she used to spend most of her time, I realised that temperature was too hot. Just under the window there was a stove outputting a hot air flow from its upper side. I asked the patient if she passed any time of the day looking outside, close to the window. As a respond she went to the window with her belly just on the out flow of the stove and told me that she used to spend hours that way, every day.
That was it! The diagnosis was "eritema ab igne". A skin disease caused by absorption of infrared radiation. Patients have an history of frequent exposure to modest heat, not enough to cause a thermal burn. At the beginning the skin is slightly erythematous but after recurrent exposures it develop the classic reticulated hyperpigmentation[2] which may be red, blue or brown. Since central heating became common, this kind of skin disorder in less frequent. In the past this matter was quite common to see, especially on the inner thighs and legs of women who stood or sat in front of stoves[3] or firesides. Nowadays we can see it due to the use of water bottles or heating pads or infrared lamps.
Erythema ab igne has been occasionally reported as a consequence of prolonged exposure to a car heater. Sometimes this condition can be the only mark of an underlying cancer if patients treat the pain caused by the neoplasm by mean of heat. Occasionally working like a baker or a forger can cause this disease.
There are some, although few, possibility that from the hyperpigmentated area a carcinoma can develop[4]. In these rare cases a squamous cell carcinoma or a Merkel cell carcinoma will arise and for this reason patients should be evaluated regularly.
The differential diagnosis to consider is "livedo reticularis" and the difference is that heat can resolve the latter situation.
Therapy consists only in avoiding exposure to the heat source. The long lasting cases maybe characterised by the persistence of an hyperpigmentated area that should be followed up to reveal a possible grow of a skin cancer.

[2] Dvoretzky I, Silverman NR. Reticular erythema of the lower back. *Arch Dermatol* 1991; 127: 405-406, 408-409.
[3] Meffert JL, Davis BM. Furniture-induced erythema ab igne. *J Am Acad Dermatol* 2000; 34: 516-517
[4] Freedberg IM, Eisen AZ, Wolff K, et al. *Fitzpatrick's Dermatology in General Medicine*. 5th ed. New York: McGraw-Hill; 1999.

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The machine which irons Parkinson

Doctors are "invited" to always mainly contain the cost of their work, the Hospitals and the Protected Residences see also the more common drugs denied, Regions raise their guillotines anti-expense... and then we discover that for Parkinson diseases these hellish machines are free!

Instructions for the use: to remain within in feet for 20' twice a day (?!).
Outcomes: absolutely not guaranteed.
Cost: probably over 700 €.
Reflection: based on which Evidence?

(photography executed by a GP of the publishing committee during a home visit to a patient with Parkinson's disease)

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Von Willebrand's Disease and Menorrhagia in women over 14 years - Descriptive research of 50 GPs

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and GPs of the Netaudit List (www.netaudit.cjb.net)

Introduction

In this descriptive study the Netaudit List wanted to test new grounds. We started to go into deeper studies concerning the relationship between the diagnosis of common and apparently ordinary disorders and the possibility of screening rare and more "classic" diseases: in our case, the relationship between "ordinary" menorrhagia on one side, and on the other, hypothyroidism and one of the most frequent genetic diseases, von Willebrand's disease.
Through the study of von Willebrand's disease, we wanted to evaluate our regular practice respect to a I level test, the bleeding test, which on one side continues being present in the most accredited texts (also because there still isn't an alternative I level test, even if there are more and more complex tests), on the other side, it tends to be disappearing from the list of quite a few Italian laboratories, not for the loss of "evidence", but because of "internal" risks (HIV, hepatitis) for the lab technicians.
TABLES 1 and 2 were used for the preliminary definition of von Willebrand's disease and of the problem of "menorrhagia "

Objectives

a) Evaluate the prevalence of von Willebrand's disease in women over 14 years.
b) Evaluate the underestimation of the disease in the patient's records both respect to expected results (comparison with epidemiological data), and respect to the omissions of I level tests in the patient's records, in particular the Time of Bleeding
c) SECONDARY AIM: Study the relationship between a spy symptom in women, menorrhagia, and the inclination to deepen the studies of two of the less known causes: hypothyroidism and Von Willebrand's disease.

Methodology

The presence of von Willebrand's disease, Menorrhagia Time of Bleeding tests and TSH were evaluated and put in the file of 50 GP's computerized patients records. Von Willebrand's disease is considered as classified only "nominally" (if in the patient record there only is the diagnosis, without the appropriate Level I or II test results), or with clear operative criteria according to the points listed in **TABLE 1**

Results

Numbers: **50 GPs** participated in the study with an average of 735,3 women over 14 years per GP, for an overall amount of 36.767 women over 14 years.
The GPs and the reference Laboratory: 16 GPS (32%) referred that their reference laboratory does not carry of the Time of Bleeding test.
The GPs and the request for a Time of Bleeding test post-ASA: Only 1 GP out of 50 referred having requested sometime the Time of Bleeding test after a dose test with ASA.
Number of von Willebrand cases with operative criteria: **4** cases (4 GPS with one only case) with a prevalence of
4/36767 equivalent each to 0,1 case each 1000 women.
Number of von Willebrand cases with nominal criteria: **7** cases, of which 5 GPS with only one case, and 1 GP with two cases. If we add up the von Willebrand cases with diagnostic criteria and with only a "nominal" diagnosis, we have 11 case out of 36767, equivalent to a prevalence of **0,29 per 1000 women** over 14 years.
Number of requests of Time of Bleeding tests in all the patient records of women over 14 years (fig. 1): 40 GPs out of 50 never requested a Time of Bleeding test. In average there is a number of 1,14 tests per GP; the average increases to 6,8 Tests for 10 GPs that required at least 1 Time of Bleeding test.

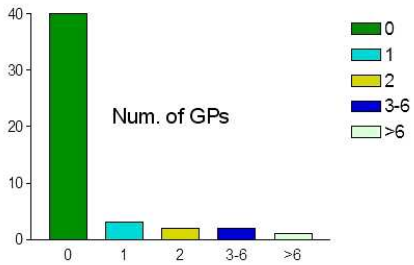


Fig. 1 : number of "Time of Bleeding" in all case histories

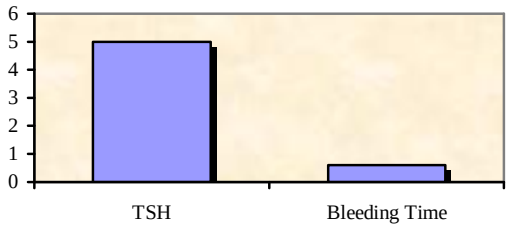
Number of cases with Menorrhagia: we found a great variability among the GPs, with a range between 0 cases and
66; 11 GPs didn't have even one case of menorrhagia in their patient records. The average is of 8,6 cases per GP; the average increases to 12,3 cases of menorrhagia per

GP, if you consider the GPs that have signalled at least one case of menorrhagia.

Number of TSH tests: the GPs that had recorded at least 1 case of menorrhagia had in their patient records an average of 5,2 cases with at least 1 request for TSH test (respect to the average of 12,3 cases of menorrhagia per GP)

Number of Bleeding Time tests for Menorrhagia: the average resulted being low: only 0,6 tests per GP with at least one case of menorrhagia; it is interesting to notice that this data is significantly ($p<0,001$) and clearly lower than the requests for TSH tests in cases of menorrhagia **(fig. 2**).

Fig. 2: Number of THS and Bleeding Time in women with at least one case of menorrhagia



Conclusions

This study which is apparently simple, encourages to set different questions. The first regards the prevalence of von Willebrand's disease: we have found **a prevalence 10 times lower** than the one referred in the most accredited publications. The reasons for these differences could be many:

a) in many cases GPs don't seem to know well the disease (see the low requests for Time of Bleeding tests and the fact that they do not request the tests with ASA)

b) during the study, we have discovered that many laboratories do not carry out the Time of Bleeding a first Level test exam

c) as you may deduce by the great number of GPs that do not have menorrhagia in their patient records and by the even greater number of GPs that do not request the "Time of Bleeding test " in cases of menorrhagia, we cannot completely evaluate the clinical value of menorrhagia alone (excessive passing on to gynaecologists?), both as evocators of the possibilities of this disease

d) we don't have the habit of evaluating first degree relatives

e) the Italian epidemiology may be different (lower) than that of other countries in which epidemiological researches were published regarding the disease (Bonardi, 1999). Further than the topic of Von Willebrand's disease, this work has shown our colleagues, in the Netaudit List, the training and research potentials in the field of rare diseases, within the setting of telematic groups of GPs.

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TABLE 1: Von Willebrand's Disease

- Von Willebrand's disease is one of the most common hereditary diseases
- and according to the most accredited publications it strikes from
- 1 % to 3% of the population (Krause, 2000;
- Lee 1999). A GP having the maximum number of patients, should expect to have among his patients at least 15 cases, of which half are women.
- The majority of these cases are tied to a dominant autosomic distress.
- Generally it isn't a severe disease; but in some cases it may show up for the first time with
- massive haemorrhages which can be life threatening. In these cases, an early diagnosis, made many years ahead, can determine a better prevention of these haemorrhages: avoiding the use of ASA and risky transfusions and the best use of ad hoc modern therapies.

Diagnostic definition

A) **FAMILY CASE-HISTORY** with the dominant autosomic pattern

B) **LABORATORY**

I Level tests: Prolonged Time of Bleeding, baseline or after stimulation with ASA (this is the test that most correlates to clinical practice. It may be carried out also after 1-2 days of "stimulation" with ASA at small doses, i.e. aspirin 100 mg for 2-3 days)

II level test:

I) reduced levels of di antigenic factor VIII or of the "RISTOCETIN" Cofactor

II) reduced functional activity (Functional Test) of the VIII factor in some patients
In the Level II tests, said multimeric factor vWF (von Willebrand Factor) comprises I and II tests.
At times, the PTT is altered (while the PT remains normal)
The platelets are NORMAL for quantity and/or function.
Symptoms and signs

- Episodes of menorrhagia, epistaxis, gingival haemorrhages; at times even more severe gastro-intestinal haemorrhages.
- Post-surgical or teeth post-extraction bleeding

(we remind that in platelet disorders, haemorrhages present themselves as petechia or purpura; in distresses due to coagulation factors, haemorrhages are most of the time intra-articular or intra-muscular)
Therapy (Preparation for surgical or dental operations)
The Therapy must be planned only after consulting the specialist and it comprises, according to the different situations, Desmopressin Acetate, Tranexamic Acid
Time of Bleeding
From Burlina: "The Time of Bleeding test, if correctly carried out, preserves, despite its simple feature, a significant importance in the diagnosis of emerging haemorrhages"
2 analytical methods:
a) Duke - Normal Values: 1-3 Minutes
b) Ivy - V.N. 5-7 minutes
Duke Technique: deep puncture 3 mm in the earlobe with a sterile disposable lancet; then absorb for 15 seconds the drop with blotting paper.
Ivy Method: 3 small incisions on the volar face of the forearm after having applied a constant pressure of 40 mm of Hg, by using the sphygmomanometer. Every 3 seconds blood is absorbed with the blotting paper.

TABLE 2: Menorrhagia
EPIDEMIOLOGY
It strikes 9-10% women.
According to some sources (Krause, 2000) 17% of women with menorrhagia and a normal pelvis examination have a hereditary haemorrhage distress; and among these approximately 2/3rds are affected by von Willebrand.
DEFINITION: An excessive quantity of menstrual flow, at more or less regular intervals, which most of the times goes on for many months-years. There could be a certain superimposition with metrorrhagia (Loss of blood during intermenstrual periods)
Some indicators of menorrhagia:
Duration over 7 days
Passage of clots
Anaemia
CAUSES and DIFFERENTIAL DIAGNOSIS:
Besides Hypothyroidism and Von Willebrand's Disease, other diagnosis (that were considered exclusion criteria by the Audit) are: uterine disorders (endometriosis, significant fibroma, incorrect position of an IUD, etc), and illness such as Stein-Leventhal Syndrome and other severe and rare causes (i.e. leukaemia)

List of the 50 participating GPs
AUGRUSO Angelo, BALESTRAZZI Marina, BARUCHELLO Mario, BATTAGGIA Alessandro, BEVILACQUA Massimo, BONETTI Dario, BOVO PAOLO, BRIZIO Enzo, CALISESI Romano, CAMPANINI Angelo, CAROSINO Claudio, CAVICCHI Gaetano, CAVONE Emanuele, CRESSONI Maria Chiara, DALLA VIA Attilio, DE BARI Antonio, DEL ZOTTI Francesco, DI PASQUALE Alessandro, DOLCI Alberto, FIORETTA Anna, FRAPPORTI Guglielmo, GIUNTI Giuliana, GRANZOTTO Stefano, GRASSI Marco, IOVERNO Enrico, LAZZARI Giorgio, LEONCINI Moreno, MARCHETTI Roberto, MAZZI Marco, MEROLA Gennaro, NARGI Enzo, NEGRINI Augusto, NOVELLA Guido, PAOLINI Italo, PAROLIN Orfeo, PASQUATO Paola, PIERANTONI Abramo, PIZZILLO Carlo, QUATTROCCHI Piero, SANI Emilio, SCHIANCHI Paolo, SIMIONI Giuliana, STRAMENGA Carlo, TARALLO Nicola, TONELLO Paolo, TORTI Giorgio, TOTA Maria Fiorenza, VANTAGGI Gianni, VISENTINI Emanuele, VISONÀ Eugenio

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Audit study on the use of ACEIs and statins in patients with risk of cardiovascular diseases

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Background

In the last years there have been two main studies on cardiovascular risk, HOPE and HPS, that have sustained the value of statins and of some ACE inhibitors (in particular Ramipril) in subjects with a high cardiovascular risk (Diabetes, Heart attack, Stroke and peripheral arteriopathy). The first idea of our Audit was to evaluate how much our clinical records were conform with the considerable HOPE and HPS studies on statins, Ramipril and other ACE inhibitors, going further on the judgment of "value" ("How much would it cost to give medication drugs to everybody? How much would our patients risk without the medication drugs?").We also wanted to complete our audit, with the analysis of other

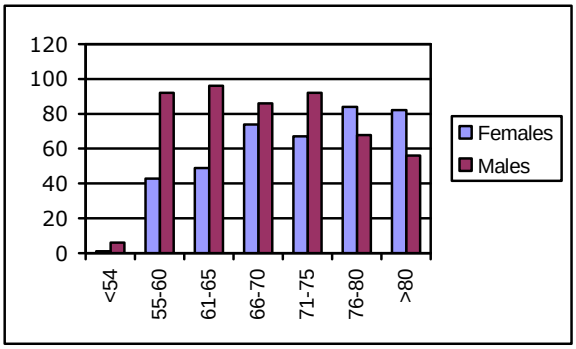
risk factors and of other basic drugs for patient prevention (e.g: ASA) in order to better evaluate the eventual absence of statins and Ramipril.

Objectives and methods

In order to plan the objective, we preliminarily interpolated the HOPE and HPS criteria (see the **Table** in the footnotes).
These are the three steps of our trial:
a) For first, in **patients of Age over 55** years, we selected **all cardiovascular or diabetic** patients (Type I or II), following the international operative criteria.
b) We then randomised for each GP a list equivalent to 60% of the patients, up to a maximum of 25 patients per participating GP. For each recruited patient, we evaluated both the main risk factors, and the chronic therapies undertaken during the last 12 months.

Materials and Methods

By means of a Self-Auditing method **36 GPs in General Practice** of the telematic Netaudit List examined **50.007 clinical records** (average patients per GP: 1389,1 ± 1,58). 25% of the GPs participating to the study has more than 1500 patients; the number of patients selected according to the extraction algorithm (all the patients with a high risk of cardiovascular disease **eligible for statins or Ramipril)** was of **2.671 subjects** with an extraction rate for 100 patients equivalent to 5,4 (I.C. 95%: 5,18- 5,62]; the index denotes a great homogeneity in the proportion of patients having the clinical conditions that were established for the study by the different GPs. The average rate per 100 assisted patients at risk and enrolled in the study results being different (in a statistically significant manner) per geographical area of the participating GPs (8% in central Italy, 5% in northern Italy and 4% in southern Italy) and doesn't result being different per dimension of the city or town.
The randomized patients, for which a patient-record was filled out, were **897** (**32,5% of the eligible patients**), sample that was significantly over the minimum representative number established for the survey. Of these patients, 44,6% was female and 55,4% was male. The average age group was 71 years and 50% of these patients had an age comprised between 63 and 77 years. The distribution per age and gender of the patients reveals a high female prevalence that is over 75 and males between 55 and 75 years of age.



The prevalence of patients with determined pathologies, risk factors or undergoing therapies among those that were selected (897) was as following:
- 22,5% for peripheral arteriopathy [IC95%: 19,9 -25,5].
- 15,8% for stroke [IC95%: 13,5 - 18,4]
- 24,4% for heart attacks [IC95%: 21,7 - 27,4].
- 13,5% for microalbuminuria [IC95%: 11,1 - 15,6].
- 70,1% for high blood pressure [IC95%: 67 - 73,1].
- 71% for diabetes [IC95%: 67,9 - 73,9].
- 45,6% for high Cholesterol levels or low HDL levels or high LDL levels [IC95%: 42,3 - 48,9].
- 13,6% is the data for the smoking habit [IC95%: 11,5 - 16,1].

Use of medication drugs

- 15,9% is the percentage of patients undergoing therapy with Ramipril [IC95%: 13,6 - 18,5].
- 9% are in therapy with sartans [IC95%: 7,3 - 11,1].
- 34% are in therapy with another ACE [IC95%: 30,9 - 37,2].
- 29% are in therapy with statins [IC95%: 26,1 - 32,1].
- 2,6% are in therapy only with fibrate drugs or resins [IC95%: 1,7 -3,9]
- 5,4% are in therapy with warfarin [IC95%: 4,0 - 7,1]
- 45,8% are in therapy with ASA [IC95%: 42,5 - 49,1]

Each one of these factors, on the basis of the characteristics of the trial, are utilized to calculate the prevalence in the general population of the patients assisted by the GPs:
- Arteriopathy: 12,1 per thousand [IC95%: 10,6 – 13,6]
- Stroke: 8,4 [IC95%: 7,2 - 9,8]
- Heart attack: 13,0 [IC95%: 11,6 – 14,6]
- Diabetes: 37,9 [IC95%: 36,3 – 39,5]
- The number of patients affected by Hypertension, Stroke, Heart attack, Peripheral Arteriopathy and Microalbuminuria **that are not treated with ACE-I** is **338**, equivalent to ***43,4%***.
- The number of patients affected by high Cholesterol levels, or low HDL levels or high LDL levels, Stroke, Heart attack or Peripheral Arteriopathy **not treated with Statins** is **380**, equivalent to ***61,2%***

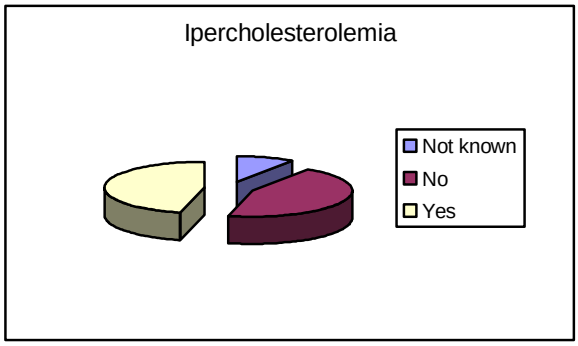
• The number of patients affected by Stroke, Heart attack or Peripheral Arteriopathy **not treated with antiaggregating** drugs is **72** (equivalent to **16,9%**).

Pathologies

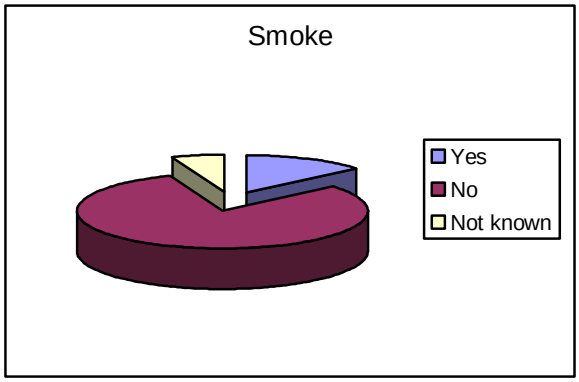
A further analysis of the **other pathologies** present in the patient record has supplied the following evidence:

• microalbuminuria is present in 13,1% of the cases, absent in 40% and was not evaluated in 46,8% of the cases

• hypercholesterolemia is present in 46% of the 890 selected cases, 44,6% does not present this pathology, while 9,4% has no data recorded in the patient record.

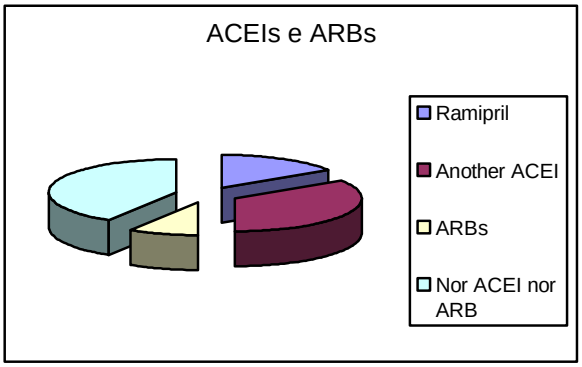


• In the group of 897 persons, 80,6% is represented by non smokers (possible signal of a good counselling made by the GPs?), 13,6% smokes and 5,8% does not have the data recorded in his clinical record.

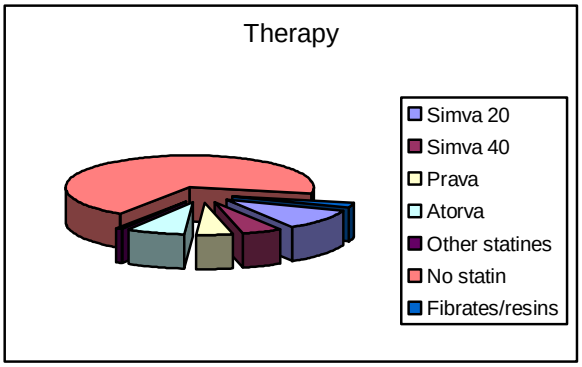


Therapies

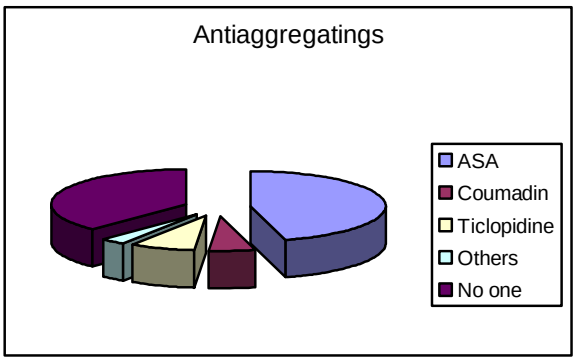
• Of the 897 selected patients, 41% does not use ACE-I or ARBS, 15,9% takes Ramipril, 9% takes ARBS and 34% the other ACE-I.



• Evaluating the therapy with statins, this risk group with 897 persons does not take any statine in 68,5% of the cases, Simvastatine is prescribed in 10,7% of the cases at 20 mg/die and in 5,2% of the cases at 40 mg/die, Atorvastatine is utilized in 7,4% cases, Pravastatine in 4,8% cases, other statins in 0,9% cases, while the use of ion-exchanging resins or fibrates is used in 2,6% of the cases.

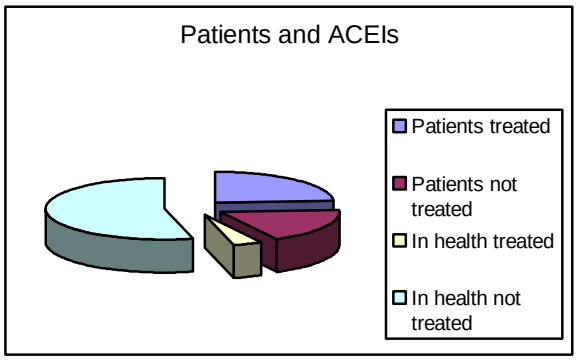


• Out of the 897 selected cases, 45,8% assumes ASA; no antiaggregating drug has been prescribed in 37,6% cases, while ticlopidine reaches 7,8% and warfarin 5,4%. Other antiaggregating drug combinations among these are assumed by 3,4% of the selected cases.



Contingencies between pathologies and therapies

The study regarding the eligibility to the treatment with medication drugs supplied some discordant data, at present, among the indications of the *trial* and prescriptive behaviour of the GPs. Analysing the therapies with **ACE-I** in subjects at risk, 338 eligible patients according to the *trial* criteria do not assume medications belonging to such category while the possible "preventive" measures of this class is utilized only by 8 patients.



Concerning the treatment with **Statins,** 68% of this group at risk made up of 897 patients (380 subjects) do not assume them, even if there are indications for their use: out of the 241 undergoing treatment (29%), only 21% assume the statins with clear indications on the prevention of CV distresses and only 5% assumes Simvastatine at the doses indicated by the HPS trial for these reasons (40 mg/die). You may also notice that the prescriptions of Atorvastatine surpass by 36% the prescriptions of Pravastatine, even if first the medication drug is missing in the Italian ministerial indications (following the significant international *trials):* effect of a good marketing campaign? Conditioning on the GPs because of the price - inferior in atorvastatine – respect to evidence?). Only 19 patients (2%) assume statins, without having the indications of a pathology (prevention), and this is the possible consequence of a long boycotting of the use of these molecules in primary prevention. 42% does not assume statins even if there is the indication to do so because of the risk factors.
353 patients utilize **Antiaggregating drugs** in presence of the risk factors we considered; almost half of the treatments take place with ASA, while 207 patients in absence of pathology utilize this category of medication drugs; therefore, there is a 23% that utilizes them as a preventive treatment and an 8 % that should be in therapy and still isn't.

Besides…

Only 32,5% of the patients extracted, have a file that has been correctly filled out in all the fields that have been established for this trial: this percentage seems to be insufficient, mainly if you consider that the participating GPs in the Netaudit are usually volunteers, motivated and presumably careful to quality in their job. This impression is corroborated also by data regarding microalbuminuria, which has not been evaluated in 46,8% of the cases. Maybe a more accurate use of good data management software and of the protocols may help to compensate for these omissions. The data regarding smoke is encouraging anyways: it wasn't recorded only in 9% of the cases and it shows that non-smokers are in a high percentage (80%) of all subjects at risk.

Conclusions

The prescriptive behaviour of the GPs in the majority of the cases does not coincide with the indications that comes from the evidence of the bigger trials, principally concerning doses and typologies of statins and ACE inhibitors more validated by the most accredited literature. Significantly more elevated is the prescription of ASA.
Seen the elevated costs of chronic therapies with statins and ACE, there is the need of a debate in the medical profession and in the society, regarding the consequences of a further medicalization of the patients at risk (what is the maximum number of drugs that the single patient wants to tolerate to reduce the risk: 1, 3, 7, …?) and on the cost/benefits balance of an eventual development of these new therapies having an elevated cost in the large number of population at risk

Bibliography

The Rami-stat audit is part of the periodical Netaudit of the Netaudit List (www.netaudit.cjb.net).
The members of the active list in Rami-stat were:
a. Set-up of the protocol and plan of the trial: Francesco Del Zotti
b. Organisational coordination: Enzo Brizio
c. Responsible for the data mask (epidata) and analysis in epi-info: Pasquale Falasca
d. Responsible for the data extraction for the simple selections and in e in SQL: Roberto Galante
e. The following members have participated in the trial:

TABLE 1: Criteria of the two Trials

a) HPS: Age 40-80 years **AND** Heart Attack **OR** Stroke **OR** Peripheral Arteriopathy **OR** Diabetes mellitus
b) HOPE: Patients of age superior to 55 years with at least one of the following disease: coronaric disease, stroke, peripheral arteriopathy, diabetes in association to other cardiovascular risks (hypertension, hypercholesterolemia, low HDL level, smoking habit and microalbuminuria).