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EDITORIAL

Mario Baruchello

Man knows the "why" for his existence, and will be able to bear almost any "how."
(Victor Franckl, Psychiatrist and Developer of Logotherapy: 1905 - 1997)

Why me?
General Practice, which we'll call "fundamental", together with medicalamental acts accordingly delegated to the various specialisms, includes consolation medical acts, reassurance, love, care, first aid and support that cannot be delegated, penalty, a definite self-reduction of the doctor to specialist of a split group. In high-tech contexts, just as and even more than in the past, the doctor's figure is important, as a unifying element of the relationship between τεχνη and the patient. Little attention to relational anthropology inspired to profound ethics risks to be paid by the human being. Only constant concern towards the "person's doctor" can save relationships and communication from a prevailing reductionism (G. Cosmacini: La Qualità del tuo medico, Laterza 1995 pag. 67)

"My separation was an unexpected tragedy for me. I would have never imagined that the love between my wife and I could get into such a painful crisis…"

"Seeing myself with this colour of hair, my skin full of freckles, the impossibility of lying in the sun with my friends …"

"I feel as if the body with that thing inside isn't mine… a sarcoma at 21 years…
I desperately look at my parents, hoping to find an answer, but all I can see in this moment
are two people whose world fell apart"

How many times did we hear or think of these things while opening our office in the morning? There are events that pour in with a strong destructive charge in our lives or in our patient's lives. How do we face them? It is difficult to "philosophically" accept an accident, illness or death of a loved one, as one of the many possible events in life, and the consolidated routine prior to the change is somehow preferable to what reality is offering, often without "consulting us" before (Consulenza filosofica e cure palliative, Luisa Sesino: Janus n. 17, spring 2005; pag. 109 -116). Even if we do not like it, we have to deal with these changes. And when the reality cannot be changed, we still can do a lot to change our attitude towards what happened to us.
This means we should "**collaborate with the inevitable**" as Roberto Assagioli, psychotherapist and father of psychosynthesis (1888 -1974) stated, acknowledging an unlimited freedom to human beings because of their ability of facing all events actively and not only passively.

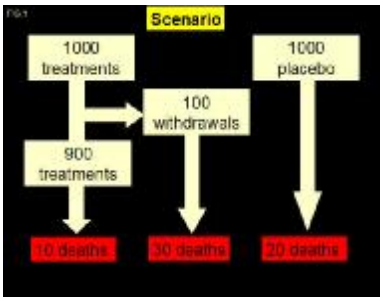
But how can we collaborate with the inevitable? How can we facilitate the management of a high-speed and….undesired change? First of all, it's important to discharge the emotions connected to the event: the most modern Emergency Rooms in the USA, those that also receive a psychological preparation, know that people who just underwent a traumatic event, must be allowed to release their charge by talking, crying or in any other way.
Contrarily to the common belief that one "must be strong" and ignore pain, it is only by discharging it through some form of expression that it can be really overcome. How many times do we unconsciously utilize this type of behaviour, belonging to the cognitive-behavioural methods of post-traumatic *debriefing* invented

by Aaaron Beck! The following step is to change attitude. From the despair of *"Why did this happen to me"*, "Why me?" pass, as soon as possible, to: *"Now that this has happened to me, what can I do?"*.
Becoming active part of the process, allows overcoming the sensation of being a victim of the events, making one concentrate his/her attention on the decision, on the actions or re-organization that should take place.
A further step is made by relativising what happened, inserting it in a broader context.
An Indian parable narrates the story of a woman, desperate for her son's death, which goes to the spiritual chief of her community, imploring him bring her child back to life. The wise man tells her that to make her wish come true he needed the shirt of a man whom had never mourned a loved one or undergone traumatic events in his life.
At the end, after having searched without success, the woman was ready to accept her fate.
But a complete "recovery" from the trauma often takes place when the person is able to "give a sense" to what happened; a step which cannot be taken "in the heat of the moment", but can be taken later, as time goes by, revealing different possible interpretations of what took place.
The Serenity Prayer presents us the best way to face those things that disturb us.
"GOD, grant me the serenity to accept the things I cannot change, the courage to change the things I can, and the wisdom to know the difference." (Reinhold Niebuhr, 1926)
This number of QQ opens with a new column coordinated by Sandro Battaggia, one of the founder members of the newsletter, whom in these years, matured significant experiences in the formation method and EBM field.
Following there are three interesting works connected to clinical field where evidence and praxis are slowly gaining popularity, within networks of relationships that need to be lubricated both with the institutions (hepatitis vaccinations) and specialists (subclinical hypothyroidism): this could explain how a selected group such as -the Netaudit members –has a low observance to the guidelines that are not too well-known.
In the end we are sure that, in relation to what I wrote above, in a near future we shall host more and more contributions that are not strictly "quantitative", but fine points of a general medicine that has a very high standard profile, tied to quality, where patient stories will make our profession seem an art that is enlightened by deep moral principles and a unique independent discipline.

WHAT IS AN "INTENTION TO TREAT" ANALYSIS?

Alessandro Battaggia, Elia Battaglia, Stefano Berardi, Isabella Fracasso, Anna Longobardi, Giuditta Motta, Giulio Rigon, Maddalena Sarti, Alberto Vaona.

Scenario
Let's imagine a research in which there are 1000 patients, affected by an incurable disease,
treated with an innovative medication drug (intervention group) and another 1000, affected by the same disease, with placebo (control group) (Fig. 1). The aim is to verify if the innovative medication drug offers advantages in terms of mortality reduction respect to the placebo.
The assignment of the patients to the two types of treatment was carried out using causal criteria: the study is therefore a Randomized Controlled Trial (RCT). The authors must record all deaths that take place in the two groups in a follow-up of 5 years, which they consider adequate for this purpose. At the end of the study, the researchers possess data on the vital state of the patients
that were enrolled. Practically:
a) Among the 1000 patients treated with placebo, 20 died.
b) Among the 1000 patients treated with the innovative therapy, 900 took it until the end of the experimentation and 100 abandoned the treatment while the study was still taking place.
c) Among the 900 patients that took the innovative therapy until the end of the study, 10 died.
d) Among the 100 patients that abandoned the treatment assigned



to the intervention group, 30
died because of a belated side effect of the medication drug.

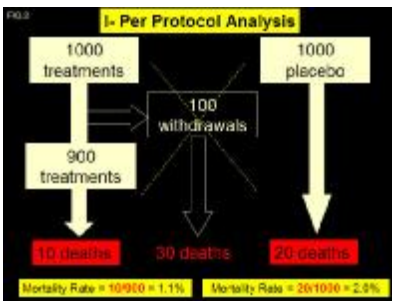
How do we interpret these results?

The first thing to do is to measure the phenomenon that is being studied (in this case: the frequency of the "death" event). The easiest technique is to calculate a simple percentage that is called
Absolute Risk of the event . The Absolute Risk of death in a group = (number of patients that dies in that group)/(sum of the patients that still are living and that died in that group).
For example, in the control group the mortality is: 20/1000 = 0.02 (2% in 5 years of observations). Now it is necessary to compare the mortality of these patients (that underwent the standard therapy) with the one in the other group.

"Per Protocol" analysis

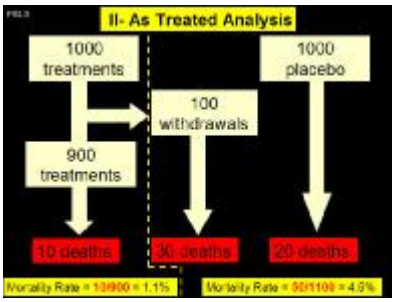
However, there is a problem. As a matter of fact, in the intervention group100 patients
abandoned the initial treatment assigned. What do we do with these patients? It would be natural to ignore them, since they violated the protocol abandoning the assigned therapy.

This analysis per groups that actually respected the protocol is called "Analysis Per Protocol". Let's calculate according to this philosophy the Absolute Risk of death (mortality at 5 years) in the intervention group:
Mortality of the patients that took the innovative medication drug respecting the protocol = 10/900 =0.011 (1.1% in five years).
Mortality of the patients that took the placebo (control group) = 20/1000 =0.02 (2% in 5 years).
From this analysis "per protocol" there is evidence that the treatment is efficient. As a matter of fact, the mortality in the intervention group (1.1%) is less than the one found in the control group (2%). However, as you can see the conclusion is distorted. In truth,



we know that 30 patients, even if they had abandoned the treatment, had died because of the belated side effects of the medication drug! At this point, do we have the right to sustain that the treatment is advantageous?

The "As Treated" analysis
This is another type of analysis that may be considered more "rational" than the previous one, which simply ignored the violations of the protocol. This means: instead of ignoring the patients that "violated the protocol", we compare the mortality of those subjects that actually took the medication drug



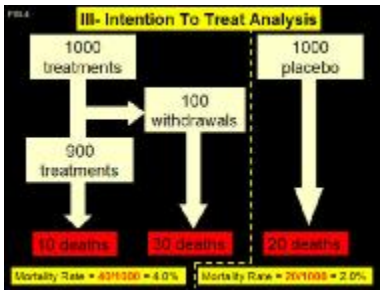
with the mortality of the subjects that actually did not take it.

The patients that took the medication drug are 900, and in this group we recorded 10 deaths. The patients that did not take the medication drug are:
a) those that were initially assigned to the medication drug but that later abandoned the treatment (100): in this group we recorded 30 deaths
b) those that took the placebo (in this group of 1000 patients we recorded 20 deaths)

This analysis based on the treatment that was actually administered is called "As treated".

Calculations are carried out as following:
Calculation of the Absolute Risk of death (mortality at 5 years):
Mortality of the patients that actually took the innovative medication drug = 10/900 = 0.11 (1.1% in 5 years)
Mortality of the patients that actually did not take the innovative medication drug= (20+30)/(100+1000) = 0.045 (4.5% in 5 years).
In our example you can observe once again that the treatment (innovative medication drug) is efficient since the mortality in those patients "that actually took the medication drug" (1.1%) is greatly inferior to the one found in the group of patients that "actually did not take the innovative medication drug" (4.5%). As you can see, proceeding this way, the conclusion is even more distorted. In fact, we know that those 30 patients that abandoned the treatment, analysed together with the control group since they did not take the medication drug, have died anyways due to the belated side effects of the medication drug!

The "Intention To Treat" analysis
In the simple example that we considered, the only way we can respect what really happened (30 deaths due to the medication drug, 30 deaths due to the disease) is to calculate the mortality within each group, comparing it to the number of patients that were initially assigned to that group.

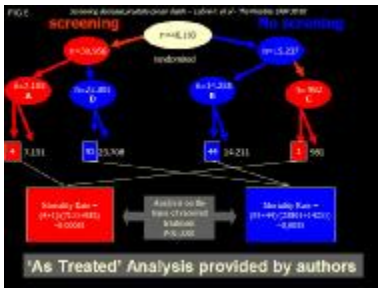


This analysis per **groups assigned by the randomization** is called Intention to treat.

The calculation proceeds as following:
Mortality in the group assigned to the intervention = (10+30)/1000 = 0.04 (4% in 5 years)
Mortality in the group assigned to the placebo = 20/1000 = 0.02 (2% in 5 years).
In this case, as you can see, the conclusions are completely opposite to those obtained in the "Per Protocol" and the '"As Treated" analysis.
What is recorded, as shown, is a higher mortality in patients that were assigned to the medication drug. In the example we considered, in the intervention group all death cases are recorded: both in patients who did not violate the protocol and patients who violated the protocol. More in detail: 1000 patients were assigned to the innovative medication drug, 1000 to the

standard treatment. Among the 1000 patients that were assigned to the innovative treatment, 30 died hegned to thenot violate the protocol and patients who violated the protocol: both (10 among those who continued taking the medication drug, 30 among those who violated the protocol).
Among the thousand patients that were assigned to the placebo, none violated the protocol and 2° deaths were recorded. This procedure does not take into account the violations to the protocol, but rather than excluding them from the analysis (as in the Per Protocol analysis), it records in each group the events that regard "compliant" patients together with the patients that violated the protocol. This type of analysis faithfully reflects what actually took place and is called "Intention To Treat Analysis" (ITT).

Comments
It is not easy for the clinician to accept an "Intention to Treat" analysis, because it appears to be irrational to consider in the calculations also events in which patients did nnot respect thr rules of the protocolot respect the rules of the protocol. However, this procedure presents a great number of advantages:
•
An ITT is the best compromise to keep intact the advantages of a randomization. A randomization has the aim o keep intact the advantages of a to render the two groups identical in the basis conditions. This way, the differences that we will observe between the intervention group and the control group will be explained by the effect of the treatment being studied. A randomization renders the twoned by the effect of the treatment being studied groups identical (provided that the number of patients is appropriate) since it distributes all known and unknown prognostic factors in an absolutely stochastic manner. On the other hand, an "as treated" analysis implies the comparison of 2 "artificial" groups, each made up by a mix of randomized patients from the two opposite groups 2. A "per protocol" analysis, excluding those patients that for one reason or another did not take the medication drug, is inevitably composed by
nnovativoprocedono così aa selectionthe case history (that of those patients which remained in the group) of the most hichof the patients that remained in theke the "resistant" for example, to the side effects of the treatment, which were verified in the illustrated scenario.
An ITT faithfully respects what takes placede in "real" conditions. The compliance to the treatment is in fact extremely variable in those patients that are observed in daily practice and it would be of no sense not to consider this, selecting for statistic comparison, a population characterized by an "ideal" compliance. A real example: does the screening of prostate cancer with rectal exploration + PSA reduce the mortality in a case of cancer?
Screening decrease prostate cancer death -Labrie F et Al The Prostate 1999 38:83-91
46193 patients, in an age group between 45 to 80 years, were enrolled in a randomized and controlled trial to explore the efficaciousness (in terms of a specific mortality reduction) of a prostate cancer screening programme. The screening was based on rectal exploration and PSA values. The mortality for prostate cancer was recorded in a follow-up period between 1989 and 1996. Among the patients enrolled in the study, 30956 were randomly assigned to the intervention group (screening); 15237 to the control group (no screening). The screening was applied to 7155 random patients within the intervention group (Group A: 4 deaths), while 23801 patients of the same group did not undergo the same procedure (Group D: 93 deaths). In the group randomized in the control group, 14255 patients followed the protocol (Group B: 44 deaths), while 982 underwent screening (Group C: 1 death). In the 8137 patients that underwent screening, 5 deaths were recorded for prostate cancer, against 137 deaths recorded in the 38056 patients that did not undergo screening.
The conclusions of the authors: (...) the study proves, for the first time, a dramatic reduction of the deaths due to prostate cancer in those patients that underwent a screening. This is a clamorous example of 'As Treated Analysis'. The data in the article (the authors do not report any loss during the follow-up period) allows to easily

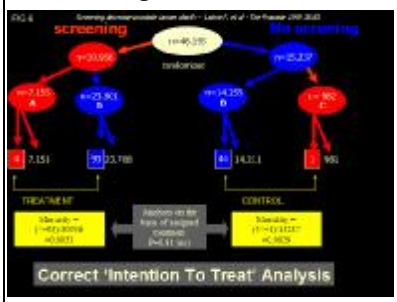


estimate the Absolute Risk of death for prostate cancer. The groups that were compared were:

Patients that actually underwent screening.
There were 7155 patients assigned to the screening randomization and compliant to this treatment + 982 patients that violated the protocol (assigned from the randomization not to undergo screening, but then they did anyways).
The overall number of patients was 7155 + 982 = 8137. In this group we recorded 4 + 1 = 5 deaths for prostate cancer. The mortality for prostate cancer (Absolute Risk) in these patients that "actually underwent screening" is 5/8137 = 0,0006144 (0,61 per ally underwentpatients waswere during amatic reduction of thearacterized thousand).

Patients that actually did not undergo screening.
These were 14.255 patients assigned from the randomization not to undergo screening (compliant to the protocol) +

23.801 patients that violated the protocol (assigned from the randomization to undergo screening, but then did not do it).
The overall number of patients was 14.255 + 23.801 = 38.056. In this group there were 93 + 44 = 137 deaths. The mortality for prostate cancer (Absolute Risk) in these patients "that actually did not undergo screening" is 137/38056 = 0.0035 (3.5 per thousand). The results are sensationally in favour of an intervention (PSA rectal exploration) in reducing the mortality for prostate cancer, with statistical significance. In the original article, the calculations are carried out using a different format (the Mortality Rate) but things do not change. In those patients that underwent screening the authors report a mortality rate for prostate cancer equivalent to15 deaths/100.0000 year/man, while in theitàvalent toa mortality nttervention control group the rate was equivalent to 48.7 deaths/100.000 year/man, with statistical significance.



If the authors, rightly, had analyzed the data on the basis of the Intention to Treat principle the groups would have instead been:

Patients randomized for the intervention group (yes screening): 30.956. In this group 97 deaths were recorded (4 among the "compliant" and 93 among the "non compliant"). The mortality was therefore equivalent to 97/30.956 = 0.0031 (3.1 per 1000).

Patients randomized for the control group (no screening): 15.237. In this group 45 deaths were recorded (44 among the "compliant" and 1 among the "non compliant"). The mortality is therefore equivalent to 45/15237 = 0.0029 (2.9 per 1000).

The difference between the two groups was not statistically significant.

Conclusions
The suitability of a follow-up is a very important requisite for the validity of a controlled experimentation. The elements that should be considered are the following:
a) The length, which must suit the need of surveying the object of the study
b) The losses at the follow-up (which must not be greater than 10% of the enrolled patients)
c) The violations of the protocol, which must be analyzed according to the Intention to treat principle.

Methodological literature (Hollis, 1999) highlights that this principle is far from being respected. As a matter of fact, the analysis of 249 articles published in 1997 says that 52% of the RCT do not report this method of analysis; and that among those that report it, 13% does not carry it out correctly.
Therefore, in the logical method field, there is still a lot to do and it would be encouraging if these concepts become familiar to those who want to consider analytically the messages of medical literature. In this article we examined the problem of violations to the protocol. In a next article we shall face another important problem tied to the follow-ups, the one with "lost" patients of whom we do not know the results

NET-ABC

Netaudit on PEOPLE TO BE VACCINATED for hepatitis B and A: markers and vaccinations for viral hepatitis in patients that are carriers of hepatitis B or C with *family contacts * for hepatitis B,

Netaudit List (www.netaudit.org)

The presence of viral hepatitis markers is tied to significant and severe diseases, whose evolution can be arrested, prescribing tests and vaccinating people in time, with vaccines that have an undoubted efficaciousness and value (for hepatitis A and B)

General aim
Evaluate the state of vaccinations in Carriers/Diseased with Hepatitis B and C and of the family contacts for hepatitis B (enrolled in our lists). Increase vaccinations against hepatitis B and A or at least a diagnostic serology or Counselling.

Exclusion criteria
a) Excludes patients that are carriers of both viruses
b) Excludes family contacts for hepatitis B that already have antibodies or have been vaccinated

Criteria taken into consideration
a) Each carrier/diseased of hepatitis B SHOULD be vaccinated for hepatitis A or at least serologically tested for hepatitis A and C. The recommendation becomes MANDATORY in case of carriers with signs of chronic hepatitis or he/she must be offered specific counselling).
b) Each carrier/diseased of hepatitis C MUST be vaccinated for hepatitis B or at least investigated anamnestically and serologically as regards to hepatitis B or he/she must be offered specific counselling.
c) Each carrier/diseased of hepatitis C MUST be vaccinated for hepatitis A, or at least investigated serologically as regards to hepatitis A or he/she must be offered specific counselling.
d) Each family contact for hepatitis B MUST be vaccinated for hepatitis B or at least

investigated on vaccinations for hepatitis B or he/she must be offered specific counselling.

AUDIT in two phases

In order to study the potential of a CHANGE only for the fields relating to vaccinations for hepatitis A or B, we collected the data on the same patients twice: the first time up to 15 March 2004; and for only 2 variables in vaccinations for hepatitis A and B, even afterwards, for other 4 months and a half, up to the 31st of July 2004.

Results

Participating GPs

The participating GPs were 27, with an overall of 37.371 patients (average of 1384 patients per GP). The 27 GPs had 833 cases at risk (2,2%), of which 379 contacts of Hepatitis B; 273 carriers or diseased for hepatitis C; 181 carriers or diseased for Hepatitis B. Averagely, each GP had 14.5 contacts, 10.1 HCV and 6.7 HBV.

Patients randomized for the Audit

In the overall 833, we randomized 237 patients (equivalent to 28%), for the "patient per patient" analysis, followed a "desired standard" of the diagnostic tests and vaccinations of 70%, and an acceptable deviation by 5%. For each randomized patient we individuated in the database the patients carriers/diseased for hepatitis B and/or C and analysed their data as regards to the serology tests and vaccinations; we evaluated in the clinical records all counselling manoeuvres; in the end, we individuated family contacts of those patients with hepatitis B that we had enrolled. Therefore, also for the contacts, we checked the above-mentioned variables –

Gender and age of the randomized patients: 119 female; 118 male. Average age: 56,7 years (DS 17,6)

Number of Carriers or diseased: 139 patients resulted being carriers or diseased for hepatitis Virus C; 61 carriers/diseased for hepatitis virus B; 37 "family contacts" (our patients) were randomized for hepatitis virus B. Among the 200 carriers of hepatitis virus B or C, 102 had clear laboratory or clinical signs of an active on-going hepatopathy.

Serology

What is recorded in the clinical record of the patients in which we indicated the research for the antibody to hepatitis A (HAV)?

In 172 cases (72.5%), with indications for the HAV test, the test was not requested; in 3 cases the test was requested, but without answers in the clinical record. In 2 cases only a counselling for the test was recorded. It was negative in 40 cases (16,8%) and positive in 21 (8,9%)

What is recorded in the clinical record of the patients in which we indicated the research for the hepatitis B surface antigen?

In 46 cases (19.4%) with indications for the test, the Australia antigen was not requested; in other 12 cases (5%) the test was requested test, but is without answer in the clinical record. In 2 cases only a counselling for the test was recorded. It was negative in 128 cases (54%) and positive in 23 (9.7%).

What is recorded in the clinical record of the patients in which we indicated the research for the hepatitis B antibody (HBsAb) ?

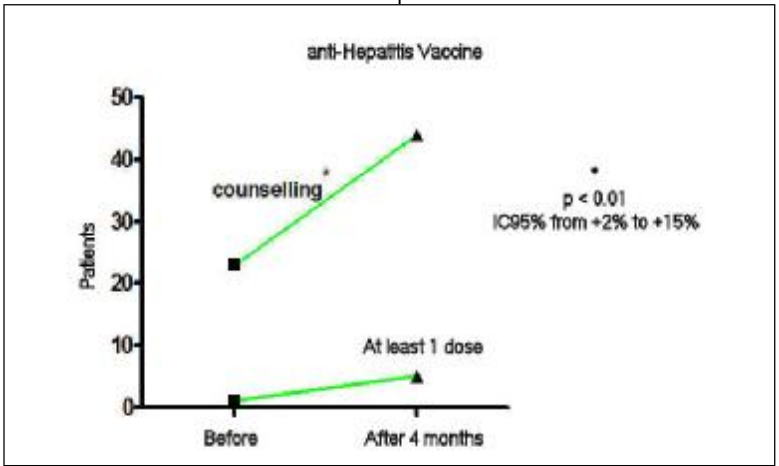
In 57 cases (24%) with indications for the test, the anti-HBs was not requested; in other 16 cases (6,7%) the test was requested, but is without answer in the clinical record. In 2 cases only a counselling for the test was recorded. It was negative in 87 cases (36,7%) and positive in 59 (24.9%)

What is recorded in the clinical record of the patients in which we indicated the research for the hepatitis C antibody (HCV)?

In 39 cases (16,5%), with indications for the HCV test, the test was not requested; in 2 cases the test was requested, but is without answer in the clinical record. In 2 cases only a counselling for the test was recorded. It was negative in 63 cases (26.6%) and positive in 57 (24.9%)

Vaccinations

Vaccination for hepatitis A, in those cases in which there were indications (evaluation carried out in two different phases, 4 months apart).



The Vaccine was indicated in 213/237 cases. In 186 cases (78.8%), with indications to the HAV vaccine, there is no data in the clinical record regarding the vaccination; at least one dosage of vaccine was recorded in at least 1 case; and the completion of the vaccine was recorded in another case. In 23 (9,7%) cases, an active counselling to the vaccination was recorded. In the IInd phase (after 4

months and a half), 5 patients had completed at least one dosage of vaccine; and 44 patients had received pro-vaccine counselling. We evaluated the differences before and after and we noticed a small insignificant difference in the number of vaccinations (at least I dose) from 1 case in the Ist phase to 5 in the IInd phase; we obtained a significant difference in the pro-vaccine Counselling: present in 23 cases in the Ist period and 44 in the IInd period: $p<0.01$ with a confidence interval of the increase from 2% to 15%.

Discussion and conclusions

During the discussion of the protocol in the **Netaudit** list, a legend emerged: vaccinations are duty of public health authorities, and not of the GP. Actually, in the same period we highlighted deep differences in the problem management of the above-mentioned structures. For example, we established that the reimbursement criteria vary from region to region, affected as they are by paradoxes that are not easy to understand; for example, in some regions serology tests and vaccinations are reimbursed to the "contacts" of hepatitis B; while vaccinations for hepatitis A and/or B for patients positive to hepatitis C are not reimbursed.

On the other hand, to balance the above-mentioned legend, what can we answer to the objections of one of our patients at-risk ("doctor, why didn't you tell to me about the vaccination?"), who contracts hepatitis B or A, maybe after years he had been a carrier of hepatitis C or a contact of hepatitis B enrolled in our Lists? At this point, nobody can deny that Quality of in this sector can easily accelerate: with a simple cycle of 2-3 injections you can solve problems of hepatitis A and B at the same time ("twin" vaccine).

In the meanwhile, we still have to go a long way in this field. More in specific, our data indicates that there still is a long way to increase serology tests and vaccinations for hepatitis B, in patients affected by hepatitis C or in the contacts of hepatitis "B"; and to spread the vaccination of hepatitis A.

Incidentally, in our study this "oversight" stands out as being proportional to the alphabetical order of the hepatitis: a serology that is disregarded more in hepatitis A, less in hepatitis B, and even less in hepatitis C.

Maybe this depends from the relatively new vaccine for hepatitis A, for which there is still little information.

Certainly, it's not up to us to "oblige" the patient to complete the vaccination cycle, principally because it is not mandatory and besides because it has a quite high cost, even if not excessive (approximately 20 euro per dose); but the discussions and the first "on the road" experiences of the list members, together with the data of our study on people to be vaccinated in 2 phases prove that, mainly for counselling, there is a good space to move towards improvement, which could maybe be reinforced by our availability to carry out vaccinations in our offices. At the same time, our evaluation of the two phase vaccinations makes us spot the incisive potential of the GP, which becomes concrete mainly for hepatitis A counselling, and for a small increase in the vaccinations.

We are convinced that an Audit carried out in two phases farther apart from one another and "focalizing" duties, will be able to give better results in the near future.

Last but not least: the contemporary GP is more and more an initiative doctor and less the doctor with "heroic" answers, a genre that is more typical in hospitals. And initiative means more anticipation, for example by

The most important serum outcomes (237 patients)

Test	Suggested but not requested	Requested, without answer	Negative outcome	Positive outcome
HAV-Ab	**172**	**2**	**40**	**21**
HBsAg	**46**	**12**	**128**	**23**
HBsAb	**57**	**16**	**87**	**59**
HCV-Ab	**39**	**2**	**63**	**57**

Vaccination for hepatitis B, in those cases in which there were indications (evaluation carried out in two different phases, 4 months apart).

The Vaccine was indicated in 213/237 cases. In 119 cases (50%), with indications to the hepatitis B vaccine, there is no data in the clinical record regarding the vaccination; at least one dosage of vaccine was recorded in at least 1 case; and the completion of the vaccine was recorded in 16 cases (6,7%). In 23 (9,7%) cases an active counselling to the vaccination was recorded. In the IInd phase (after 4 months and a half), 6 (2,5%) patients had completed at least one dosage of vaccine;16 cases (6,7 %) had completed the vaccine; and 30 cases received pro-vaccine counselling (12,6%). Regarding the difference between the Ist and IInd phase you can notice some small insignificant differences: 5 counsellings more and 2 vaccine completions more; the counsellings carried out went from 24 to 30 patients.

means of efficacious vaccinations for hepatitis, able to change the infective epidemiology of our patients and their relatives.

Bibliography

We are particularly grateful for the precious clinical-epidemiological suggestions supplied by
Prof. Vento –Infective Disease in Borgo Trento (Verona)

List of the GPs that participated in the Netaudit:

Coord.: F. Del Zotti, E. Brizio
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AMIODARONE AND HYPO-THYROIDISM

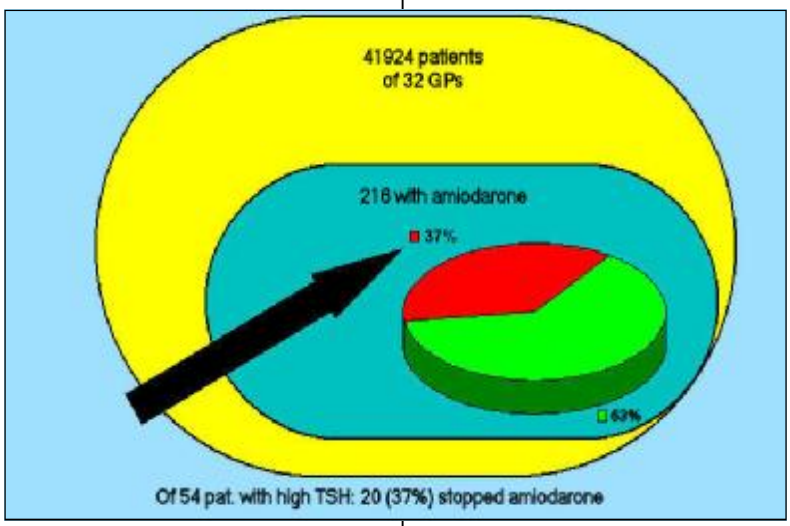
Attilio Dalla Via (PD), Angelo Cervone (NA) and Giovanni De Luigi (TO) and Netaudit List (www.netaudit.org)

Introduction

The number of arrhythmic patients in therapy with amiodarone is increasing. Obviously we can expect to see an increase of secondary hypothyroidisms. In these cases, it is spontaneous and logical to suspend the amiodarone. But is this behaviour is supported by international literature? It doesn't seem so, from the moment that various authors sustain that in these cases of secondary hypothyroidism it is sufficient to add a small dose of levothyroxine, without suspending the amiodarone1,2. We therefore wanted to analyze how the GPs of the Netaudit List behave respect to the problem.

Results

32 GPs participated in this audit. They assist overall 41924 patients (an average of 1310,1 patients per GP) and follow 216 patients in chronic therapy with amiodarone (an average of 6.7 patients taking amiodarone per GP). 54/216 (25%) patients taking amiodarone encountered a TSH >4.5 mUI/ml at least once. Among these 54 patients, amiodarone was suspended in 20 cases (37%).



Conclusions

The number of patients that suspended the amiodarone was quite high, also in presence of a threshold of 4,5 chosen by us, which is quite low and closet to an asymptomatic hypothyroidism rather than a clinically direct one; and even if the indications of the most accredited literature indicate the usefulness of not suspending medication drug, but rather giving also low doses of thyroid hormone. Apparently, our choices are affected by our fears and "modern-defensive" legends, which give power to the automatism "side effect - elimination of the medication drug". At the same time, we think that the suspension is also due to the modest diffusion among the GPs of accredited guidelines on how to manage amiodarone, which often, and erroneously, is considered prerogative only of cardiologists. The insufficient results of our audit will push our group to repeat it in two phases, about a year from now.

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SUB-CLINICAL BUT NOT UNDER-TREATED HYPOTHYROIDISM

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Design and analysis coordination: F. Del Zotti (VR), E. Brizio (CN),

Background
Subclinical hypothyroidism has a significant prevalence in MG. Yet we have the impression that the therapy, frequently given by a specialist, is not optimal. In particular, from different sources, there is who sustains that hypothyroidism is over-treated.

General aim
a) Evaluate how we manage patients that have values higher than TSH>4.5 mUI/ml
b) Among these patients, individuate the variables in the clinical records that can make us distinguish subclinical hypothyroidisms from clinical ones.
c) Analyze how/how much we treat subclinical hypothyroidisms respect to clinical ones.

Inclusion criteria
The case was included if there was at least one TSH>4.5 and clear laboratory tests that indicated a thyroiditis and/or clear signs/ symptoms of a thyroid problem; or at least two values of TSH >4.5.

Exclusion criteria
A) Hypophysial HYPOTHYROIDISM;
B) Malignant thyroid cancer
C) Patients are hypothyroid from an excess of TAPAZOLE;
d) Goitre, without hypothyroidism

Method
We analysed the clinical records in the period prior to MARCH 1st, 2004, which means before we started to discuss the idea in the Netaudit List. Regarding the questions on the eventual CHRONIC THERAPY "*does the patient use a thyroid medication drug*" and the one regarding the "*maintenance dose*", we observed the period of 12 months before MARCH 1st, 2004. Each GP first evaluated all patients and then, record per record, up to maximum 15 randomized cases, taken from the list of patients with TSH>4.5.

Results
33 GPs belonging to the national Netaudit list participated in the audit. These GPs assist 45.647 patients, an average of 1.383 per GP. The patients with TSH > 4.5 were **878**/45647 (equivalent to 1.9%, with IC from 1.8% to 2%) and therefore, an average of 26.6 patients per GP.

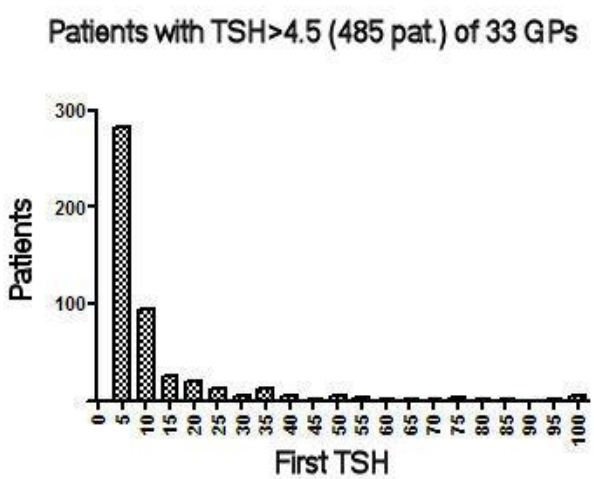
Randomization
To honour the Netaudit slogan (Audit in less than 3 hours only for GPs), we did not analyse all the 878 patients with TSH>4.5, but just a representative random sample. Using a randomization with 3% of tolerated error and maximum uncertainty of the considered criteria (50%), we obtained a group of 482 patients. The Netaudit List analyzed the single clinical records of a random sample that was greater that the minimum suggested, which means: **485 patients with TSH>4.5**.

Age, gender and BMI of the 485 randomized patients, of which 403 female (83%) and 82 male (17%). Average age: 54,2 years. The average BMI of the patients was 26.8 (SD 5.4)

Frequency of the TSH test The major part of patients with a TSH greater than 4,5 were followed regularly:377 patients (79.9%) received a request for a TSH test in the 12 previous months; for 64 patients the last TSH dates back 12-24 months; for 29 patients the last TSH was tested 24 months before; in 5 cases the datum was missing.

TSH and FT4
The average of the first pre-diagnosis "historical" TSH in a clinical record was of 12,4. From **Figure 1** you can notice that the majority of the patients has values around 5 micrograms. The average of the first FT4 was of 17 ng/dl with only 95 cases (19%) having values of hypothyroidism, which means under 0.84.

Pict. 1

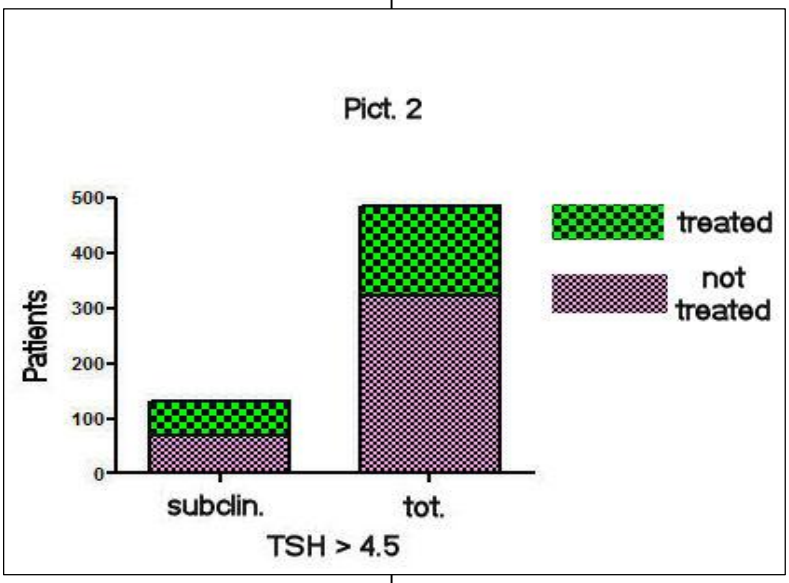


Presence of antithyroid antibodies
Only 176 patients (36,3%) had in their clinical records clear

alterations in their antithyroid antibodies.

Presence of symptoms

225 patients (46.4%) were asymptomatic. 149 patients (30.7%) were partially symptomatic. The remaining patients were symptomatic.



Which causes?

Among the different causes there seems to be thyroiditis (164 cases); then multinodular goitre (80 cases); non-neoplastic surgery (33); the use of Amiodarone (26); previous hyperthyroidism (25). The diagnosis was absent or not clear in 154 cases.

Which therapy?

Majority of the patients used levothyroxine 316/485 (65.2%): 6 patients used another thyroid hormone; 162 patients were not treated (33.5%)

What was the dosage among the 316 patients treated? 58/485 patients took more than 100 micrograms (µg); **105**/485 patients from 75 to 100 µg; **87**/485 patients from 50 to 75 µg; **66**/485 patients from 25 to 50 µg.

How many patients have a suspect of subclinical hypothyroidism?

The moment of the data analysis, adapting some bibliographical indications, we individuated the area of suspected subclinical hypothyroidism in the cases that combined cases a triad of "**TSH<10** AND **FT4 in a normal range (greater than 0.84)** AND **absence of clinical symptoms**". Therefore we individuated **131**/485 patients (27%; CI 23% - 31%) with all three characteristics.

61 out of 131 of these patients with subclinical hypothyroidism are undergoing hormone therapy **(Figure 2**). Among these 18 patienAs take from 50 to 75 µg levothyroxine/die and 19 take more than 75 µg levothyroxine.

Conclusions

From the data analysis comes, on one side a relative frequency of subclinical hypothyroidism (27%), on the other a real risk of over-treatment. Actually, in a group of patients with TSH that is slightly higher and lower than 10, and with a normal and asymptomatic FT4, 46.6% takes hormones and often at medium-high dosages, and goes against the current trend of the most accredited indications and guidelines that tend to suggest no medication and only a cautious wait-and-see policy. We still must find the reasons for this over-treatment. Maybe it could be in the excessive delegation to 2nd level Medicine, generally more interventionist than the 1st level one. Actually these "subtlety" in the differential diagnosis seem to be documented by the high rate of unclear diagnosis in the clinical records, and seem to distance GP's tasks. On the other side, if the GP was helped by continuing education and by computerized systems, to recognize the many subclinical hypothyroidisms, it would be easier to use a congenial weapon: patience in observing in time, instead of the categorical imperative of "always treat".

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NetAudit List (www.netaudit.org)

Members of NetAudit attended to study:

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Grey Herons
Waterpencil by Marco Grassi
GP in Santarcangelo (RN)