The tubercular disease in immigrants without documents: new diagnostic settings adopted in Milan, Italy

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Abstract

The tubercular disease (TB) is "the disease of poverty and people in need", spread in the poorest countries and among the less wealthy people of the western world (immigrants). In Italy the health authority has recently defined precise diagnostic and therapeutic patterns for TB. The social and health Association Naga in Milan with the Regional Reference Centre for TB, designed a screening system. In Naga's surgery all the undocumented immigrants, coming to Italy from countries with high TB incidence (> 100/100000) and high immigration rates, are screened by a questionnaire created by the Swiss Lung League; the suspect cases are sent to a designed centre for a second level of investigation. The use of this form allows to set a first selection based on the patients' anamnestic history, thus avoiding the intradermal reaction that, due to its low selectivity, could cause a 4 times higher crowding of the designed secondary centers.

Introduction

According to the recent report from WHO (World Health Organization) *"Global Tuberculosis Control 2010"* (1), tuberculosis (TB) is the most spread infectious disease in the world, and considered "the disease of poverty and people in need". More than two billion people (a third of the whole world population) are affected from the tubercular infection, while more than 1.7 million people die every year from tubercular disease. TB strikes the poorest countries and the lowest social classes in the rich countries; such classes are mainly made of immigrants, TB being spread especially among the illegal ones. Thus TB is still a very serious health problem for immigrants both for the individual and the community: and its perception is sharpened by contradictory information likely to create disorientation and further fears (2, 3). During the last years in Italy the public health authority paid particular attention to the tubercular disease, setting precise guidelines with the article 115 subsection 1b of the law n. 112, 31st March 1998 and the two following *Consensus Conferences* (2006 and 2008), updated according to

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the most recent international knowledge. The *Consensus Conferences*, realized according to Murphy method M.K. (4), on *"the effective strategies for the prevention of tuberculosis among immigrants from highly TB endemic countries"*, were held in Rome. The *Consensus Conferences* have become part of a wider project for the revision of the Italian guidelines for the tubercular disease, coordinated by the National Infectious Diseases Institute "Lazzaro Spallanzani" of Rome.

Naga in Milan is an Association of volunteers for the promotion of the right to health and the fundamental rights of foreigners and nomads in Milan. Naga carries out more than 16.000 visits/year to undocumented immigrants, and represents a peculiar observatory and an important center for TB early diagnosis.

Methods

According to the decision of supporting the guidelines issued from the last Consensus Conference - June 2008, Naga has established to fully respect the *"strong recommendations"* therein included, leaving out, as suggested, the operative choices of the *"weak recommendations"* (5).

The first strong recommendation emphasizes the *"need of identifying strategies to improve the immigrants' access to the health structures. This goal is attainable provided that:*
- Information on duties and rights is supplied as well as.
- Information on how to find the right places and people.
- Services are reorganized."

The items a) and b) are carried out at Naga during the preliminary interview between the immigrant and the reception volunteer who listens to the patient's needs and fills the general information in the

form, while item c) is carried out in the continuous action of Naga to check and improve the public health services.

The third strong recommendation is relevant to the *"programs of active search of tubercular disease cases. This can be made through early diagnosis in symptomatic subjects, early diagnosis in asymptomatic subjects and search of people who have been in touch with a TB case.*

1 a) early diagnosis in symptomatic subjects:

For each new patient coming from high risk countries (rate estimated by WHO > 100 cases/100.000) doctors must:
- Give information on the risks of tuberculosis.
- Collect the data for a tubercular anamnesis.
- Investigate on the possible presence of symptoms of tuberculosis.

In case the anamnesis or the symptoms are positive a chest X-ray must be proposed" (5).

In order to carry out this first part of the third recommendation Naga has adopted the following steps.

Informative signs to be placed in the waiting room with drawings and scripts quoting the 4 signs and the 2 ways of possible infection or reactivation, as per the "border form" used by the Swiss Lung League" (6) (Figure 1). This test allows to select high risk asymptomatic patients or patients with mild symptoms, at the first appearance of the disease. The early use of the form at the border should be reserved only to people seeking political asylum (usually in more precarious health conditions owing to the travelling and/or their recent life situation) or to those immigrants in hard troubles. We are aware that the "healthy immigrant" is likely to be stricken by tuberculosis during the second, third year from his arrival.

Fig. 1 - Diagnosis of tubercular disease questionnaire (source: Swiss Lung League)

For foreigners in need of any visit at Naga who are known to come from a country listed among the 16 countries with the largest immigration rate in Italy, and, among those, from one of the countries with a TB incidence estimated by WHO >100 cases/100.000 (Ecuador, Philippines, India, Moldova, Peru, Romania, Senegal, Ukraine, non-Mediterranean Africa"[1], Bolivia and Bangladesh[2]), doctors will:

- supply short info on TB risks;

- collect the tubercular anamnesis (basing it on the "4 signs" and the "2 ways of possible infection or reactivation", as per the already mentioned "form") and will fill in the special diagram in the case sheet with the relevant score (1 for each "sign" and 2 for the two 2 "situations"). If the score is >/=2 (or in any case if there are suggestive symptoms) the patient will be sent to the second level structures Regional Reference Center Villa Marelli, Milan, for a visit of a specialist and a chest X-ray, if necessary for further microbiological tests as well. If the score is equal to 1 the patient will be asked to come back. Each patient with a positive score will be registered in a special file with name, surname and telephone number. For recurrent patients the research is to be repeated once a year.

All this in addition to the usual examination required by the patient.

"1 b) early diagnosis in asymptomatic subjects

For the asymptomatic subjects the research of the infection and the tubercular disease has been proposed to people coming from high risk countries (incidence estimated by WHO > 100 cases/100.000), immigrants living in Italy since less than 5 years or more, but in a hard socioeconomic situation; the reference test is the tuberculin test, with Mantoux method. However this test has proved to have a low specificity: El Hamad *et* al. reports a positivity to Mantoux test equal to 39,1%

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[1] The concept of "non-Mediterranean Africa", has been formulated by Naga because there is the highest TB rate, even if this region has not a high rate of immigration to Italy.

[2] From our data a considerable flow of immigrants from Bolivia and Bangladesh has been recorded in the last recent period.

in 2006 among the immigrants living in the county of Brescia (7).

This test is considered a "weak recommendation" as per the definition given by the *Consesus Conference*, since it doesn't meet the cost/benefit criteria, that's why Naga doesn't use it.

"2) Search of people who have been in touch with a TB case

Search of people who have been in touch with a TB case represents the priority screening action among immigrants for:

- the cost/benefit ratio;
- the possibility of gaining access to the immigrants' community in a less intrusive way;
- the high acceptance of the treatment.

Naga is not directly involved in such activity that is to be carried out by ASL (Azienda Sanitaria Locale-Local Health Services); sometimes, especially for Gipsies, Naga is requested to cooperate owing to our deep knowledge of the local nomadic settlings.

The second and the fourth strong recommendations are not quoted here: they deal about the compliance to the antitubercular treatment and the vaccination with Bacille Colmette-Guérin vaccine (BCG) in children: these subjects are not dealt with by Naga for its peculiar mission.

Therefore according to the statement of the 2008 *Consensus Conference*, Naga realized, further to the first recommendation regarding the strategies to improve the immigrants access to the health structures focusing:

- the early diagnosis of the tubercular disease among undocumented immigrants coming from countries with TB incidence higher than 100 cases/100.000
- restricting it to immigrants coming from geographic areas with a high migratory flow to Italy, and

- using the "border form" for the first level screening designed by the Swiss Lung League.

The realization of the TB Project was started at Naga in June 2009 and the first months were used to define the screening. The current data refer to the period 1st January – 31st December 2010.

The survey was carried out collecting the following parameters:

- number of patients visited at Naga in 2010 (first level visits);
- number of patients likely to be examined for TB, according to the already mentioned criteria (i.e. immigrants coming from highly endemic countries and countries with the highest migratory flow to Italy);
- number of patients who were not included in the survey, because coming from highly endemic countries but with a low migratory flow, (this survey is meant to check their "negligibility" in numerical terms[3]);
- number of patients really examined at Naga for TB, and number of patients not examined for our organizational reasons;
- number of negative scores (= 0);
- number of positive scores (= 1), patients invited to be visited again after 1 month;
- number of positive scores ($\geq$ 2), patients sent to second level structures;
- compliance of patients who have really accepted the invitation of a further visit later.

Results

In 2010 in our surgery a total of 14574 visits have been carried out to undocu-

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[3] This group is not included in this screening program to simplify the survey method, because it is considered not important.
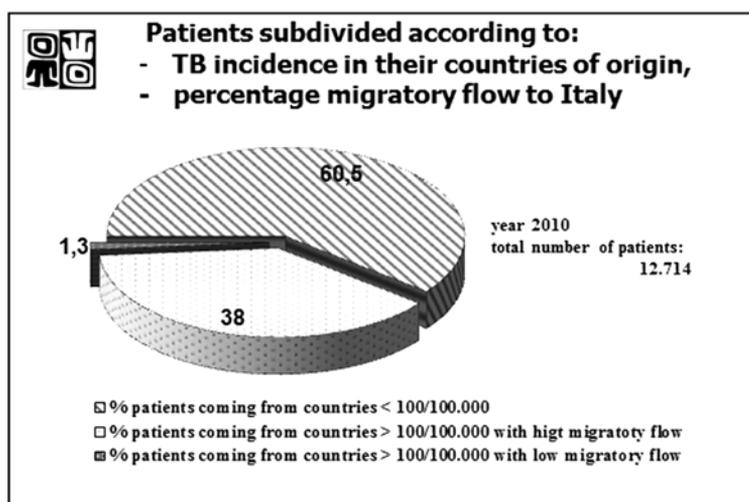
Fig. 2 - Patients, TB incidence in their countries of origin and percentage migratory flow in Italy

mented immigrants. Actually these data include a small number of occasional visits to regular immigrants or Italian citizens (< 0.1%).

In the period between the 1st January and 31st December 2010 the first level visits for the undocumented immigrants were 12714. Within this group , 4838 patients fulfilled the criteria we had established for the screening through the questionnaire (i.e. patients coming from highly endemic countries and high migratory flow) (Figure 2).

Among 4838 patients coming from highly endemic countries and high migratory flow, 1005 (20.8%) were sorted random to be screened. Among these 1005, 51.1% are males and mean age is 36 years (34.4%: 25 - 34 years; 28.9%: 35 – 44 years; 17.6%: 45 - 54 years; 10.4%: 16 – 24 years and greater than 54 years are 8.7%).

The Peruvians are the largest ethnic group of the sample (22.6%), followed by Romanians (12.9%), Ecuadorians (8.8%), Senegalese (8.8%) and Ukrainians (8.5%) and the remaining ethnic groups amounted to 39.8% .

These data (which are only people with an incidence of tuberculosis > 100/100.000), are substantially similar to those observed in previous socio-demographic surveys conducted in 2002 and 2008, population-based immigrant, belonging to the Naga.

Through the screening of 1005 patients, we have identified 854 (85%) patients with score 0, 46 patients with score 1(4.6%) and 105 with score 2 or > than 2 (10.4%). Moreover during the visits to the group of patients coming from low endemic countries (i.e. < 100/100.000), we have found 20 cases in need of further examinations for tubercular disease; they were sent to a second level centre as well.

No patient refused to be examined. No patient refused to come back a month later (for scores equal to 1) and to be re-examined c/o a second level centre (for scores 2 or > 2).

Only 11 of the 46 patients with a score = 1 (23.9%) came back spontaneously a month later, as agreed: in all of them the new examination established that the new score was reduced to zero. The others

were called on the phone: 21 of them (45.6%) were found and had negative results as well.

The second level investigations, carried out in the Regional Reference Centre Villa Marelli-Milan, in the period between January – December 2010, highlighted the following results:

4 cases of tubercular disease (3.8%),

44 negative cases (41.9%),

57 patients (54.2%) who have not come back (they have been called again by phone).

The regional centre looked after the 4 affected patients and carried out a preventive treatment for the patients not affected by active TB, but with Tuberculin Skin Test (TST) >10 mm, and younger than 35 years, as per the regional protocol. The centre experience shows that, among these immigrants, the preventive treatment, lasting 6 months, is achieved in 72% of the cases (8).

Conclusions

The aim of our research was to outline a method able to put into operation the decisions of the 2008 *Consensus Conference*, i.e. to define an updated screening method for the early diagnosis of the TB to be used for a high risk population, due to their status of undocumented immigrants. The early diagnosis of the tubercular disease is actually a focal point: the reduction of the time between the symptoms onset and the diagnosis/treatment (currently 6 months) is a decisive issue for the health either of the individual person and the community (reduction of the infection period). The examined sample allows to achieve the above mentioned aim; the same sample results to be numerically inadequate for an analysis of the tubercular problem in such population: this was not our aim.

In the "questionnaire" we have identified a test suitable to replace the traditional tuberculin test in the first level survey, this one requesting a longer time (check to be planned after 48-72 hours), more expensive (5 €), not specifically targeted (it only highlights an immunity situation, that is however widely spread, while the questionnaire identifies a current and restricted risk, either anamnestic or clinic).

The data collected during the survey highlight the following conclusions.

The first level screening, based on the use of the "questionnaire" to the immigrants coming from highly endemic countries (rate > 100/100.000), but limited to the countries with the highest migratory flow to Italy, allows to easily identify a limited group of populations, only excluding from the screening a population numerically insignificant (1,4%), that in our case includes Russian, Belorussian, Afghan, Nepal, Mongolian, Indonesian and Pakistani immigrants. These data are subject to further reduction if, according to the surveys to be held in the next months, Pakistani immigrants will be included among the populations to be screened (they currently represent 0,63% of the population living in Italy). Pakistan has an incidence of tubercular disease much higher than 100/100.000, but so far it is not included in the list of countries with a high migratory flow to Italy; our most recent data highlight however a clear upward trend of this flow. Afghanistan appears to be in a similar situation.

Finally, while revising the list of populations more affected by TB in Milan a proposal of including Moroccan immigrants in the said list was made because a high number of TB cases was found during the surveys carried out in the second level centres in our region, in spite of the relatively low incidence of TB in Morocco (in any case < 100/100.000).

The survey is carried out in an easier way thanks to the fact that the survey can be limited to a definite and rather narrow number of populations, ethnically characterized. We notice that little less than 40% immigrants we have visited come from TB high risk countries.

On the whole the test has selected a population equal to 15% of all the questionnaires distributed, partly to be checked again after one month c/o our centre (4,6%) and partly (10,4%) to be sent to a second level centre for further analyses. The workload for the second level centre is 4% of the whole population we have examined. This result appears to be very interesting when compared with other screening methods, still used by other centres (such as the tuberculin test): recent experiences carried out in our region show that according to this test, that gives positive results in about 40% of the examined patients, a population ten times higher than the one selected through the questionnaire would be sent to a second level centre for further surveys should the tuberculin test be applied to everybody; should this test be applied, in a way similar to ours, only to the immigrants coming from highly endemic countries a number of immigrants nearly four times higher than ours would be sent to the secondary level centres that would be heavily affected in their activity.

Only 23.9% of the patients due to come back to our surgery for a further check of "score 1" have volunteered to show up; a further 45.6% were recalled by our operators on the phone.

Only 45.3% of the patients due to the second level centre volunteered to show up (we are still waiting for data relevant to the others who were called back by phone).

The above mentioned data concerning the poor willingness of the immigrants to accept further checks confirm what we already were aware of. We deem it essen-tial to get ready and plan further phone follow-ups to remedy this behaviour that might compromise the screening effectiveness. Moreover this attitude of refusing further checks is another good point in favour of the questionnaire in comparison with the tuberculin test.

The first level screening, in theory affecting 100% of the population meeting the criteria we have defined, results to be reduced in our survey because it depends on a surgery activity that can't be easily planned, due to communication problems with some groups of immigrants, emergency situations, missing records etc. The result is that instead of doing a research among a population of 12714 immigrants only 20,8% of them were examined, that is 2645 individuals.

The method we have designed for the early diagnosis of the TB in undocumented immigrants, consists of a systematic level of care, towards to everybody aiming at identifying the people who have the first signs of tubercular disease (by means of the questionnaire and the possible second level investigations). This method is simplified thanks to these two elements:

- to be able to focus the attention to the people coming from high endemic countries (following the WHO recommendations);

- to focus the attention on patients coming from countries with the highest migratory rate to Italy (WHO and Naga data).

Critical issues

A further investigation will be made in the future about the immigrants' reaction, before and during the visit, to a problem different from the one, apparently the most important one, that led them to the surgery.

We'll also check whether the annual repetition of the investigation, as per our recommendation, is effective or not.

The effectiveness of the first level screening method through the questionnaire, already proved by the Swiss surveys, can be further checked by revising the cases dealt with by the second level reference centre in Milan (Villa Marelli): no case considered as negative after being screened at Naga should exist among the cases treated later by the reference centre for tubercular disease.

Riassunto

La tubercolosi negli immigrati illegali: nuove procedure diagnostiche adottate a Milano, Italia

La tubercolosi (TBC) è "la malattia della povertà e della vita disagiata", diffusa negli Stati più poveri e fra le classi meno abbienti del mondo occidentale (immigrati). In Italia, negli anni recenti, l'Autorità sanitaria ha delineato precisi percorsi diagnostici e terapeutici per la TBC. L'Associazione socio-sanitaria Naga di Milano, assieme al Centro Regionale di Riferimento per la TBC, ha messo a punto un sistema di screening A tutti gli immigrati privi di documenti che accedono all'Ambulatorio di base del Naga, provenienti da paesi con tasso di malattia tubercolare >100/100.000 e ad alta immigrazione in Italia, viene somministrato, dal medico, il "questionario" messo a punto dalla Lega Polmonare Svizzera; i casi sospetti sono inviati all'indagine di secondo livello presso il centro di riferimento. L'utilizzo del questionario permette di praticare una prima selezione su base anamnestica, evitando di ricorrere all'intradermoreazione, la cui bassa selettività determinerebbe un afflusso ai centri di secondo livello 4 volte maggiore.

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