ORIGINAL ARTICLE: IMPROVING PRACTICE EFFICACY

The appropriate counseling on prenatal screening test for foreign women in Emilia-Romagna

Daniela Menichini¹, Giovanna Sciutti², Maria Vittoria Miano², Alba Ricchi², Ramona Infante², Maria Teresa Molinazzi², Emma Bertucci³, Fabio Facchinetti³, Isabella Neri^{2,3}.

¹International Doctorate School in Clinical and Experimental Medicine, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Italy. ²School of Midwifery Department of Medical and Surgical Sciences, University of Modena and Reggio Emilia, Italy. ³Obstetrics and Gynecology Unit, Mother-Infant Department, Policlinic Hospital, University of Modena and Reggio-Emilia, Italy.

Abstract. Objective: The increase in the migratory phenomenon entails the need to adapt obstetric care to the population which includes foreign pregnant women. In this context, it emerged a little adherence to the prenatal screening test among foreign women compared to Italian women, which is assumed to be attributable to an inadequate counseling. Therefore, the objective of this study was to evaluate the midwife's perception regarding the effectiveness of the counseling offered to foreign women for the combined test and subsequently assess its adequacy through an evaluation by an external operator. Methods: this is a cross-sectional study conducted from September to November 2019. An ad hoc questionnaire was administered to midwives who work in the territorial district of the Emilia-Romagna Region, investigating their counseling skills. Then an external evaluation of the counseling was conducted by observing the interview between the midwives and the patients (N = 10), to analyze its appropriateness. *Results:* Seventy-five midwives completed the questionnaire with a positive response rate of 57.2%. In general, 69.3% of midwives are satisfied with the training received from the regional course, but 85% found many difficulties in counseling foreign women. The 14% of midwives state that they always have the cultural and linguistic mediator available and 44% of them state that they use brochures translated into several foreign languages. In the interviews observed, the counseling for prenatal screening offered to foreign women was found to be shorter and more limited than that provided to native women. Conclusions: Most of the consulting midwives declare that they feel prepared to perform a correct prenatal counseling also for foreign women, but the external evaluation of the interviews, and the regional data on adherence to the antenatal screening of foreign women, show many critical points. It becomes necessary to carry out further studies that investigate not only the counseling skills of midwives, but also the needs of assisted women about prenatal diagnosis.

Keywords: Combined test; prenatal screening; counseling; midwives; foreign women; pregnancy.

Introduction

In the last decade the evolution of knowledge and technologies in the prenatal field has determined a huge demand from pregnant women to perform prenatal screening tests which, although not diagnostic, are able to offer reliable results in terms of "estimating a risk" using non-invasive approaches. The combined test is currently considered, among the screening tests provided for by the 2011 Guidelines for physiological pregnancy, the one with the greatest sensitivity to estimate the risk of contracting major fetal chromosomal abnormalities, i.e. trisomies linked to chromosomes 21, 18 and 13. This test is considered reliable if performed within the 13th week of the gestational period (1).

It consists in combining maternal dosages of β -HCG and PAPP-A with a fetal ultrasound for the evaluation of nuchal translucency (NT) together with other maternal parameters. The result of the examination, calculated by a special software, expresses in the form of a percentage of risk, the probability that the fetus is affected or not by one of the three syndromes. Its detection rate for trisomy 21 is approximately 83% (1).

This test has become part of the essential levels of assistance since 2017 (2) and most of the Italian regions, including Emilia-Romagna, have therefore made it free during pregnancy. Despite this, there are many women who do not benefit from this service, especially among foreigners.

The data extrapolated from the last report of the year 2018 on the foreign population in Emilia-Romagna carried out by the Regional Observatory on the migratory phenomenon, show that 14.8% of newborn in Italy and 24.3% of new born in Emilia-Romagna is of foreign origin (3). The largest foreign community is that from Romania with 17.4% of all foreigners present in the territory, followed by Morocco (11.3%) and Albania (10.6%) (3).

From the birth certificates of 2018-2020 of Emilia-Romagna, it emerged that the foreign population adheres significantly less (-26%) than the Italian population to both diagnostic and screening prenatal investigations (4-5).

Objectives

Given these premises, the present study intends to evaluate the adequacy of the counseling that obstetric staff carries out to foreign women for adherence to the combined test, then investigating what are the factors that influence the discrepancy in the adherence of foreign women to the methods of prenatal investigations and in particular in adherence to the combined test.

Material and methods

Study design and protocol

This is a cross-sectional study aimed at improving the quality of the counseling for antenatal care by using a questionnaire for midwives working in the territorial clinics of Emilia-Romagna Region (61 clinics). In the period from September to November 2019. The clinics are located throughout Emilia-Romagna and can reach a large user base by offering all pregnant women consistent, up-to-date, and completely free obstetric care (6).

Internal evaluation of counseling: the questionnaire

To evaluate the perception that midwives have of the counseling on prenatal screening test offered to foreign women, an *ad hoc* questionnaire was created for midwives, consisting of 16 multiple choice questions relating to 4 macro-areas: personal information and work experience; formation; main contents of the counseling carried out and the approach to foreign users.

Regarding the education and training of midwives, they were asked not only the type of training they had carried out (online courses, masters, individual training), but also if they were satisfied with the skills acquired and, if not, if they had carried out further insights into the scope.

The question about the content of the counseling was structured by listing all the information to be provided to the woman during the interview and asking which were the 3 most important (offering 6 options).

In the section relating to the counseling offered to foreign women, the midwives were asked what critical issues were encountered during the counseling with these patients, what were the most difficult topics for them to explain and for users to understand and what tools were available in the counseling center (translated brochures, cultural linguistic mediator).

The questionnaire was administered online to midwives operating in the Emilia-Romagna territorial clinics (131 counseling midwives). The questionnaires were kept anonymous, and the responses were processed with Google forms.

External evaluation of counseling: prenatal counseling in the clinic

To assess the adequacy of counseling, we integrated the information collected with the questionnaire with an external evaluation of the counseling offered by midwives to foreign women. Thus, an external operator (part of the research group) attended the prena-

| 1 | Age (years) | | |
|-----|------------------------------------------------------------------------------------------|----|-------------------------------------------------------------------------------------------------------|
| 2 | Working place | | |
| | vvoiking place | | less than 1 year |
| | | 0 | 1 year |
| 3 | Years of service on the territory: | 0 | 2 years |
| | | 0 | 3 years |
| | | 0 | more than 3 years |
| 4 | Year from which the Physiologica Pregnancy follows independently: | | |
| | | 0 | Delivery room |
| | | 0 | Hospital ward |
| 5 | Previous work areas: | 0 | Pregnancy outpatient clinics in the hospital |
| | | 0 | Freelance Profession |
| | | 0 | None other |
| | | 0 | |
| | | 0 | online course of the Emilia-Romagna Region online course from another institution |
| | Training carried out to indepen- | 0 | 1st level Master |
| 6 | dently follow the Physiological | 0 | 2nd level Master |
| | Pregnancy: | 0 | None |
| | | 0 | Other non-academic training course |
| | Do you think your training is suf- | | |
| 7 | ficient to perform effective coun- | O | No Yes |
| | seling on prenatal diagnosis? | 0 | ies |
| 8 | Have you ever done additional | 0 | No |
| | training to fill these gaps? | 0 | Yes |
| 9 | If YES what kind of training? | | |
| | | 0 | Explain what the prenatal screening tests proposed by the NHS specifically investigate |
| | | 0 | Explain the concept of screening and its difference from a diagnostic test |
| | Indicate among these points the | 0 | Explain the screening reliability rate |
| 10 | three that are most important to | 0 | Explain the concept of risk linked to that of reliability |
| | you in the counseling process: | 0 | Explain the clinical procedure and the most appropriate methods of carrying out the |
| | | _ | gestational period and the method of carrying out the procedure Signature of informed consent |
| | Do you find it more difficult to | 0 | Signature of informed consent |
| 11 | explain these points to foreign | 0 | No |
| 11 | women than to Italians? | 0 | Yes |
| | | 0 | Spoken language different from that of the operator |
| 12 | If YES what do you think is the | 0 | Culture of belonging even in couples who understand the language used for counseling |
| | reason for this difficulty? | 0 | Level of education of the couple |
| | | 0 | Explain the pathologies specifically investigated by the prenatal screening tests proposed by the NHS |
| | Which of these points do you think is more difficult for the foreign user to understand? | 0 | Explain the concept of screening and its difference from a diagnostic test |
| 13 | | 0 | Explain the screening confidence rate |
| | | 0 | Explain the concept of risk linked to that of reliability |
| | | 0 | Explain the clinical procedure and the most appropriate methods of conducting it with |
| | | | respect to the gestational period and the method of carrying out the procedure |
| | | | Explain the pathologies specifically investigated by the prenatal screening tests proposed |
| | Which of these points do you find most difficult to explain to the foreign user? | ł | by the NHS |
| 1 4 | | 0 | Explain the concept of screening and its difference from a diagnostic test |
| 14 | | 0 | Explain the screening confidence rate Explain the concept of risk linked to that of reliability |
| | | () | Explain the concept of fisk iniked to that of feliability |
| | | 0 | Explain the clinical procedure and the most appropriate methods of conducting it with |

| Tab | le 1. Ad hoc questionnaire administe | erec | to midwives |
|-----|-----------------------------------------------------------------------------------------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 15 | What tools do you have available to deal with counseling with foreign women? | 0 0 0 | Linguistic-cultural mediation always and immediately available Linguistic-cultural mediation only if booked in time Telephone linguistic translation always available even in the absence of a mediator Information brochures translated into language |
| 16 | What tools do you concretely use in your daily practice to deal with counseling with foreign women? | 0 0 0 | I have the woman sign the adhesion to the screening program and book the appointment, postponing any further explanations to the day of the exam Use of the information brochure translated into the language provided by the Region before obtaining consent, leaving the woman time to understand its contents and express any concerns Use of information brochure translated into language provided by the Region after having already obtained consent I request the presence of a cultural mediator in advance before obtaining consent, but only if the woman does not speak the Italian language I request the presence of a cultural mediator in advance before obtaining consent, even if the woman speaks the Italian language I use the simultaneous translation of a relative of the woman to carry out all the counseling I use a very simplified but at the same time effective language to explain the key concepts of screening |

tal counseling carried out during the first obstetric visit in one of the major clinics in the region, the Piacenza family clinic. This choice was mainly linked to the organization of the study and made it possible to reduce intra-operator variability. During the study period, 10 first obstetric visits to foreign women took place.

The interviews were analyzed through a qualitative observation carried out by the researchers and then transcribed as faithfully as possible. Subsequently, a checklist defined based on the contents expressed by the information SIEOG - Italian Society of Obstetric and Gynecological Ultrasound was used to evaluate as objectively as possible the completeness and adequacy of each interview in the context of screening tests and prenatal diagnosis.

counseling for the prenatal screening

Data Analysis

The variables collected were processed using the statistical software Stata 16.1 (StataCorp LLC, Texas USA).

Statistical tests were designed to compare the impact of maternal socio-cultural and economic variables on adherence to the combined test between Italian and foreign pregnant women. Comparison between groups was performed using a 2-tailed Student's t-test or a 1-or 2-way analysis of variance, followed by the post hoc Newman-Keuls multiple comparison test.

Continuous data are reported as mean \pm standard deviation (SD). Categorical data were reported as ratios and percentages. All probability values were 2-sided and a P <0.05 was considered statistically significant.

| Table 2. Assessment checklist for the evaluation of counseling | | | |
|----------------------------------------------------------------|-------------|-------------|----------------------------------------------|
| INFORMATION TO BE GIVEN TO THE PATIENT | YES | NO | NOTE |
| What is prenatal screening (combined-test) | | | |
| What is a chromosomal abnormality (trisomy 21,13,18) | | | |
| Advantages of the test | | | |
| Limitations of the test | | | |
| Test reliability / risk concept | | | |
| Operating modes to perform it | | | |
| Paper material provided in support | | | |
| Signature of informed consent | | | |
| The checklist has been created based on the SIEOG (Società | Italiana di | Ecografia O | stetrica e Ginecologica) requirements on the |

Results

From the analysis of the birth certificates (CedAP), foreign women who gave birth in Emilia-Romagna in 2018 were 11,103 (33.7%). Among these, the most represented nationalities were Tunisian (1.1%), Nigerian (1.4%), Moldovan (1.5%), Pakistani (1.6%), Albanian (3.7%), Romanian (4.9%) and Moroccan (6.6%).

Comparing the adherence to the combined test of foreign women with that of Italian women, we see that in 2018 the 62.9% of the total of Italian pregnant women adhered to the combined test, while only 42.8% of foreign women did so. If we consider also the data relating to the execution of invasive investigations, the gap between the two samples is even greater.

Characteristics of the population from the birth certificates (CedAP)

A total of 21,851 Italian women and 11,103 foreign women gave birth in Emilia-Romagna in 2018.

The average age of Italians is around 33 years, while for foreigners it is slightly lower with an average of 29.9 years. The most represented level of education is the high school diploma for both Italian women (9,823) and foreign women (4,328)

The marital status shows a small numerical difference between married and single women in the group of Italian women (51.3% married vs 48.7% single), while it shows greater diversity in the group of foreign women who are 76.8% married and only 23.2% are single.

Finally, there is a clear difference in the two population groups with respect to the choice of the operator or clinic that follow the pregnancy. Only 37% of Italian women choose to be followed in a clinic against 80% of foreign women. Foreign women rely on the care of a private doctor only in 13% of cases, unlike Italians who make this choice in 58.4% of cases.

Internal evaluation: results of the questionnaire

The ad hoc questionnaire, that focused on the

| Table 3 Adhesion of Italian and Foreign women to prenatal screening and diagnosis (Chi square test) | | | | | |
|-----------------------------------------------------------------------------------------------------|--------------------|-------------------|---------|--|--|
| | Italians (N=21851) | Foreign (N=11103) | P value | | |
| No prenatal screening | 6151 (28.1%) | 6.034 (54.3%) | 0.006 | | |
| Combined Test | 13745 (62.9%) | 4755 (42.8%) | 0.006 | | |
| Villocentesis without combined test | 1255 (5.7%) | 151 (1.4%) | 0.002 | | |
| Amniocentesis without combined test | 700 (3.2%) | 163 (1.5%) | 0.002 | | |
| NIPT | N/A | N/A | N/A | | |

Table 4. Maternal socio-demographic characteristics (Student t test e Chi square test)

| | Italians (N=21.851) | Foreign (N=11.103) | P value |
|-----------------------------|---------------------|--------------------|---------|
| Mean age | $(33,0 \pm 5,3)$ | $(29,9 \pm 4,8)$ | 0.0000 |
| Education level | | | 0.0000 |
| Low (< 10 years of school) | 422 (1,9%) | 661 (6%) | |
| Middle school (10-13 years) | 2.985 (13,7%) | 4.117 (37%) | |
| High school (13-18 years) | 9.283(42,4%) | 4.328 (39%) | |
| University | 9.161 (42%) | 1.997 (18%) | |
| Martial status | | | |
| Married | 11.207 (51,3%) | 8.525 (76,8%) | 0.0000 |
| Single | 10.644 (48,7%) | 2.578 (23,2%) | |
| Number of visits | | | |
| 0-4 | 1.230 (6%) | 1.609 (14,5%) | 0.0000 |
| > 5 | 20.621(94%) | 9.494 (85,5%) | |
| Pregnancy followed by | | | |
| Territorial clinics | 8.076(37%) | 8.887 (80%) | 0.0000 |
| Public hospital services | 1.005 (4,6%) | 730 (7%) | 0.0000 |
| Private practitioners | 12.770 (58,4%) | 1.486 (13%) | |

training of midwives, the key concepts of counseling, the difficulties encountered with foreign couples and the tools used by midwives to help these couples better understand the screening of prenatal diagnosis, was administered anonymously to 131 consultatory midwives. The response rate was 57.2%, for a total of 75 midwives who completed the questionnaire. Table 5 shows the most relevant results.

The most important points of the counseling, according to midwives were: the explanation of the difference between a screening and a diagnostic test (72.4%), the explanation of what prenatal screening tests specifically investigate (63.2%) and the description of the clinical procedure and its method of implementation (44.7%).

Regarding the tools and methods used to facilitate counseling with foreign women, the midwives were asked which ones they used during counseling with foreign women. 82% of them have the linguistic-cultural mediator available only if booked in time, while 14% have the mediator always available. Information brochures translated into the language are used by 43% of midwives.

External evaluation: the results of the interview

Two researchers from the study team observed the 10 first visits in order to externally assess the quality of counseling, following the checklist created based on the SIEOG (Italian Society of Obstetric and Gyneco-

| Table 5. Questionnaire results. | | | |
|-----------------------------------------------------------------------|----|------------------------------------------------|-------------|
| Relevant Questions | OI | otions | N (%) |
| Education | | | |
| Training to independently follow the Physiological Pregnancy | A. | Emilia-Romagna Region online course | 63 (84%) |
| | В. | Online course from another institution | 0 |
| | C. | 1st level Master | 0 |
| | D. | Second level Master | 0 |
| | Ε. | None | 1 (1, 3%) |
| | F. | Other non-academic training course | 11 (14, 7%) |
| Do you think your training is sufficient to perform effective coun- | A. | Yes | 64 (85,3%) |
| seling on prenatal diagnosis? | В. | No | 11 (14,7%) |
| Concepts considered most important in counseling | | | |
| Indicate among these points the three that are most important to | A. | Difference in screening / diagnostic exam | 55 (72,4%) |
| you in the counseling process (multiple choice): | В. | Pathologies investigated by the screening | 48 (63,2%) |
| | C. | Methods of carrying out the procedure | 34 (44,7%) |
| | D. | Screening reliability rate | 21 (27,6%) |
| | Ε. | Concept of risk and reliability | 14 (18,4%) |
| | F. | Signature of informed consent | 10 (13,2%) |
| The difficulties encountered with foreign couples | | | |
| Do you find it more difficult to explain these points to foreign cou- | A. | Yes | 64 (85,3%) |
| ples than to Italians? | В. | No | 11 (14,7%) |
| If YES, what do you think is the reason for this difficulty? | A. | Culture | 32 (49,2%) |
| | | Language different from that of the operator | 25 (38,5%) |
| | C. | Education level of the couple | 8 (12,3%) |
| Strumenti utilizzati | | | |
| What tools do you have at your disposal to deal with counseling | A. | Linguistic mediation always | 11 (14,7%) |
| with foreign women? | В. | Linguistic mediation by reservation | 62 (82,7%) |
| | | Telephone language translation always | 15 (20%) |
| | D. | Information brochures translated into language | 26 (34,7%) |
| What tools do you use in your practice to deal with counseling with | A. | Consent without effective counseling | 2 (2,7%) |
| foreign women? | | Information leaflet before consent | 29 (38,7%) |
| | C. | Information leaflet after consent | 1 (1,3%) |
| | D. | Cultural mediator before consent | 10 (13,2%) |
| | E. | Relative or acquaintance | 17 (22,7%) |
| | F. | . Very simplified language | 37 (49,3%) |

logical Ultrasound) requirements for prenatal screening counseling.

Three visits were carried out with patients of Italian nationality, while the remaining 7 with patients of the following nationalities: 2 Egyptian, 2 Guinean, 1 Moroccan, 2 Albanian.

In two cases the information material translated into the language was provided, but only one of these two women had the time to consult it.

The average time for the entire visit, including personal and family medical history, general pregnancy information, nutritional and prenatal counseling was 35-40 minutes for all women. Specifically, the time devoted to counseling on antenatal investigations was no more than 4 minutes per patient.

Discussion

In Emilia-Romagna, the adherence to the combined test by foreign women is significantly lower than that of Italian users. The data collected from the questionnaires administered to the midwives showed conflicting information: on the one hand the midwives agreed that the advice on prenatal diagnosis is certainly more difficult if carried out with foreign patients, on the other few of them knew they had tools at their disposal, as brochures translated into several languages to support counseling. Additionally, nearly the half of midwives relied solely on the use of simplified language to convey complex content.

Furthermore, midwives have found it more difficult to explain the concept of prenatal screening to foreign women also because of the different cultures they belong to (7-8). Finally, only 30% of employees admitted the need for further training in prenatal counseling.

As far as the visits observed are concerned, it emerged that midwives are more interested in understanding whether the woman wishes to perform the combined test and less in investigating whether the woman is actually able to give an informed consent for this examination. In fact, the time spent explaining the prenatal diagnosis during the interviews was very short, equal to about 4 minutes per patient.

The examination is defined in several interviews as "non-abortive" and is presented almost as "routine" and not dangerous in any way for the mother-child. The non-invasiveness of the test was also used during an interview as a reason to persuade a woman uncertain of compliance to participate in the screening.

On the contrary, midwives have systematically omitted: the explanation of the clinical effects on pregnancy of a test with a "high risk" or "intermediate risk" outcome; the explanation of the consequent invasive follow-up with amniocentesis or chorionic villus sampling necessary to have a diagnosis of certainty starting from a result that suggests a possible greater risk of chromosomal abnormalities (9).

These shortcomings are partly configured as important notional errors, but also and above all as difficulties in approaching the user's ethics, which could lead to serious medico-legal implications for all professionals involved in the case of legal disputes following diagnosis. unexpected chromosomal abnormalities (10).

The information on prenatal screening tests must in fact always allow the patient to understand the possibility of changing his mind with respect to the choice

| Table 6. Interviews' results | | | | | |
|--------------------------------------------------------------|--|--|--|--|--|
| Women with little knowledge of the Italian language (N=4) | | | | | |
| | | | | | |
| n) | | | | | |
| n) | | | | | |
| 6) | | | | | |
| n) | | | | | |
| n) | | | | | |
| n) | | | | | |
| | | | | | |

made and must at the same time deal in detail for each examination: benefits, limits (false positives and false negatives) and implications in case of positive test (11). It is necessary to consider the fact that in 25% of cases of women with little knowledge of Italian, the adhesion was made by the husband independently without the wife being involved.

Conclusions

Most midwives report feeling prepared to perform adequate prenatal counseling, however, the data collected in this study go in the opposite direction.

According to this cross-sectional study, midwives need further theoretical training and, above all, their practice must be supervised, assessed and certified as adequate or not. Furthermore, if we consider that the health system in Emilia-Romagna is at the forefront in Italy, and the territorial assistance to provide is efficient, it is not difficult to estimate how also in other Italian regions there could be situations similar to that source in this study. It is therefore necessary to carry out further studies that investigate not only the counseling skills of midwives, but also the needs of assisted women about prenatal diagnosis.

In conclusion, antenatal screening counseling should not be limited to the transmission of scientific knowledge on a topic but should consider the need of each woman to take into account her socio-cultural differences.

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Correspondence:

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Daniela Menichini

Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Italy

Largo del Pozzo, 71, 41125 Modena

e-mail: daniela.menichini91@gmail.com

ORCID ID: https://orcid.org/0000-0002-8531-7124