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Translation validation and adaptation to the Italian cultural context of the pregnancy sexual response inventory

Maria Luisa Rega ^{1,*}, Gloria Cassisi ², Michelangelo Danza ^{1,3}, Gloria Anderson ², Antonio Lanzone ^{1,2}

¹ Università Cattolica del Sacro Cuore, Rome, Italy.

² Obstetrics Pathology Unit, Department of Woman's Health Sciences of the Child and Public Health, University Clinic Foundation "A Gemelli" IRCCS, Rome, Italy.

³ Department of Obstetrics and Gynaecology, University Clinic Foundation "A Gemelli" IRCCS, Rome.

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*Corresponding author: Maria Luisa Rega, RN, PhD. Università Cattolica del Sacro Cuore, Largo F. Vito 1, 00168, Rome, Italy. Email: marialuisa.rega@unicatt.it. ORCID: 0000-0003-3276-944X.

ABSTRACT

Objective. The aim of this study was to translate, validate and adapt to the Italian context the Pregnancy Sexual Response Inventory, an instrument for assessing the sexual health of pregnant women.

Materials and Methods. The process was based on WHO guidelines that involved four different phases: Forward translation, Expert panel Back-translation, Pre-testing and cognitive interviewing, Final version. For the pilot study, a sample of 37 women was recruited between October and November 2020 at the Policlinico Universitario "A. Gemelli" in Rome. A Likert scale was used to qualitatively represent women's sexual health. The Student's t-test and Cronbach's α were calculated.

Results. Good statistical significance was obtained for each item ($p < 0.05$). Cronbach's α (0.78) showed excellent internal consistency and reliability of the instrument.

Conclusions. The Italian Pregnancy Sexual Response Inventory (PSRI) represents a useful tool for the detection of sexual health problems in pregnant women.

INTRODUCTION

Pregnancy defines a distinctive period in a woman's life, in which hormonal, bodily and social changes occur and affect her physical well-being, mood and interpersonal relationships [1, 2]. These changes also affect indirectly the health of the couple, whom is living a new experience [3].

One aspect of health that is particularly affected by the advent of pregnancy is sexual health. Sexual health, according to the WHO is "a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive

and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence" [4].

Sexuality involves many aspects in a couple's life, and during pregnancy it can also be influenced by one's own culture, social and demographic factors, religion, level of education, duration of marriage or relationship, and also gestational age [5, 6]. Therefore, all these factors can create discomfort within the couple, modifying and altering the normal course of sexual activity during pregnancy.

Over the years, a variety of different studies have tried to describe sexuality in pregnancy and the

possible factors that modify it. These include a decrease in desire, satisfaction and frequency of sexual activity [7, 8]. 86%-100% of couples remain sexually active during pregnancy but there is a decrease in libido and frequency in the first trimester. There are slight changes in the second trimester, but this reflects the best period for sexual health, for cessation of body changes and related disorders. Finally, the third trimester is the worst trimester in terms of couples' quality of sexual life, due to an increase in sexual dysfunction and a greater decrease in the frequency of intercourse [9-11]. The causes of these changes are not entirely clear, not only hormonal and bodily changes, but as written above, there are various factors that influence sexual health.

Despite the frequency of these problems during pregnancy, health professionals still report a number of obstacles when discussing about sexual health with their patients. There is still embarrassment, misconception and discomfort to talk about sex [12]. This discomfort derives from different social, cultural and mythological beliefs. According to some couples, sex during pregnancy can damage the foetus, cause a preterm birth or a miscarriage [13].

Obviously, the safety of sexual activity is guaranteed in women with a physiological pregnancy, in fact the presence of a high risk does not allow to address this topic in equal measure. Women who have been diagnosed with a high-risk pregnancy are often advised to limit sexual activity or abstain completely from this [14, 15].

Knowledge of this phenomenon is due to the presence of a wide range of questionnaires and tools for assessing the sexual health of women and men [16, 17]. There are numerous questionnaires for the evaluation of sexual dysfunction, but to date, in Italy, there is no tool for the evaluation of the sexual activity of pregnant women, therefore validated exclusively on pregnant women, excluding Pregnancy Sexual Response Inventory [18]. PSRI has been originally validated in Brazilian and English, and subsequently has been translated into Portuguese [19]. It is a tool designed to assess sexual activity before and during pregnancy. It has been designed to identify and address any sexual problems, it is also used by health professionals, not only to assess the quality of sexual life of pregnant women, but also to identify any need for counselling of couple regarding this problem.

The rationale of this study is to introduce a specific tool for pregnant women in Italy, which is able to assess sexual health within the couple, before and during gestation, in order to identify which and how

many problems occur during this period. The scarcity of scientific material on the subject in Italy highlights the need to expand knowledge of sexual health in pregnancy during the usual gynaecological/obstetrical examinations. The dissemination of this problem, and its possible methods of intervention, would consequently improve the quality of life of pregnant women and the relationship with their partners. Through translation, validation and adaptation to the Italian cultural context of the Pregnancy Sexual Response Inventory [18], this problem will be solved.

MATERIALS AND METHODS

The aim of this study was to translate, to validate and to adapt to the Italian cultural context the Pregnancy Sexual Response Inventory [18]. In order to carry out this procedure, we followed the WHO guidelines [20]. The systematic and scientific nature of these guidelines for the validation process allow to minimize linguistic, semantic and above all cultural differences that exist between the original language of the instrument and Italian language.

The WHO translation and validation process involved four different phases:

- First translation from the original language into Italian.
- Back-translation from Italian to the original language.
- Pre-test of the Italian version.
- Final Italian version,

After the consent of the original authors of the scale, translation process was carried out by Italian and English native speakers, with the help of a bilingual panel of experts, including gynaecologists and obstetricians.

The first phase was carried out by two native Italian speakers. From this first step, several Italian versions of the original PSRI scale have been produced, extrapolated from the original article in English entitled "Design and validity of a questionnaire to assess sexuality in pregnant women" [18]. After the review by the panel of experts, and the detection of any lexical-syntactical discrepancies or inconsistencies in the translation, two other translators, this time native English speakers, without ever having consulted the original scale, carried out the second phase of back-translation, that is the English translation of the previous Italian language versions developed in the first phase. Then the two translations obtained in the

latter process were compared and any differences present were highlighted.

After that the best translation was obtained, next stage of pre-testing took place, so the questionnaire translated into Italian was distributed and tested for its validity and to reliability, through a cross-section pilot study.

The validation and adaptation study of the tool was conducted in full compliance with the latest revision of the Helsinki declaration. All the information provided for the purpose of the investigation are strictly confidential in accordance with the GDPR 679/2016 and the privacy decree Legislative Decree 101/2018. This study promoted by Università Cattolica del Sacro Cuore of Rome, also obtained the authorization from the ethics committee of the Fondazione Policlinico Agostino Gemelli in Rome, on 14 October 2020, which was entrusted with the protocol number ID 3518. Spatial and temporal setting for the study has been respectively the Department of Obstetrics and Gynecology, Fondazione Policlinico Universitario "A. Gemelli" (FPG) IRCCS in Rome, Italy, between October and November 2020.

After consulting some guidelines [21, 22], a convenience sample was recruited among the eligible patients according to the pre-established inclusion and exclusion criteria. The inclusion criteria of this study were: Italian women, on childbearing age and pregnant, equally distributed in the three trimesters of pregnancy, capable of understanding and willing, without psychological or psychiatric problems, who have given their consent to the study by signing the appropriate form and women without medical and obstetric pathologies that make sexual intercourse inadvisable.

The exclusion criteria were as follows: women of citizenship different than Italian one, women unable to understand and want, with psychological or psychiatric problems. Many studies have shown that some mental illnesses and also the use of psychopharmacotherapy can alter sexual well-being [23-25]. The study also excluded women with medical and obstetric pathologies that make sexual intercourse inadvisable, with a diagnosis of placenta previa, women with the threat of childbirth preterm, women which have had antepartum bleeding, and which were suffering from endometriosis [26], which can also compromise the psychological health of the pregnant woman [27], and other pathologies such as vulvodynia [28], vulvar vestibulitis [29], vaginismus [30], multiple sclerosis [31], Sjögren's syndrome [32].

Participants were confident that the survey was anonymous and that their responses would be kept strictly confidential for experimental purposes only. In respect of their privacy, a dedicated space within the clinics was also placed at their disposal, in which additionally to the explanation of the objectives, of the rationale and of the modalities of participation in the study, procedure for completing the questionnaire was illustrated. Answering the questionnaire required approximately 10 minutes.

As soon as the women expressed their interest in participating, a full report of the study was provided, in accordance with the safety regulations following the SARS-CoV-2 pandemic, for the consent to participation and processing of personal data. Each of the participants was also offered the opportunity to subsequently receive the research results obtained.

The distribution of the questionnaire was always carried out by the same midwife, in this way each sampled woman was given the opportunity to always address the same person for any uncomprehended word or doubt regarding this study.

Based on a pre-existing questionnaire, the Pregnancy and Sexuality Questionnaire [33], only describes the relationship with the partner during pregnancy; otherwise Pregnancy Sexual Response Inventory is a questionnaire which describes and relates the sexual habits of women and couples before and during pregnancy.

It consists of 38 questions, 12 which are about demographic traits and 26 are about sexual and behavioural activity before and during pregnancy [18, 19].

The study variables are ordinal, continuous and discrete. Specifically, the 12 demographic questions concern: maternal and paternal age, gestational age, partnership status, level of education, religion, employment, maternity, smoking, alcohol and drug use, planning of pregnancy and the use of contraceptives. Among the 26 questions concerning sexual activity, 11 of them concern the period before pregnancy, and 15 concern the gestation period.

Questions about sexual behaviour were also grouped into 10 domains. Eight of them rate women's feelings and two of them rate women's perception of their partner's sexual interest. The 10 domains are respectively: frequency of sexual activity, desire, pleasure, orgasm, satisfaction, dyspareunia, initiation of intercourse, female sexual difficulties, woman's perception of her partner's sexual satisfaction and finally woman's perception of her partner's sexual difficulties (**Table 1**). The table shows the questions grouped for each domain and for each reporting period.

For the analysis of the data, distribution were performed the Kolmogorov-Smirnov test and the Shapiro-Wilk test, both of which were significant because the data did not distribute normally. An analysis was performed for the identification of univariate outliers, which were absent in the sample.

Ordinal demographic variables were described by their absolute and percentage frequency. Continuous variables were analysed by calculating mean and standard deviation. Qualitative variables, which describe sexual behaviours before and during pregnancy, were measured using Likert scale, with values expressed in quartiles from 0 to 4. The cut-offs of the scale, which reflect sexual health of the sample, are:

1 = 0 to ≥ 25 as "very bad".

2 = 25 to ≥ 50 as "bad".

3 = 50 to ≥ 75 as "good".

4 = 75 to ≥ 100 as "excellent".

Scores below 50 reflect altered and poor sexual health status, and therefore scores higher than 50 reflect a good or excellent state of health.

A score was calculated for each domain in both periods considered. Question number 20 was not subjected to the evaluation scale, because it is consequential only to an affirmative answer to the previous question number 19b.

In order to identify the difference in sexual health's quality in relation to the period before and during pregnancy, an average of Likert's scores for each domain was also worked out, it was determined by the sum of all the specific domain scores for each period, divided by the total number of domains. A single value has been obtained, which express

the generic sexual health's status for both periods analysed by the PSRI.

Finally, the hypothesis test Student t-test was performed among the values of each domain for both periods analysed, using a significance level of 5%. A significance of the P-value < 0.05 was also considered. The internal consistency and reliability of the instrument were assessed by calculating Cronbach's α .

The results of the study were collected through an Excel Office 15 database, and SPSS (Statistical Package for Social Science), version 21.0, was used for their subsequent statistical analysis.

Analysis of the sample's power was elaborated to define the sample size [21, 22].

RESULTS

The outcome of the study was the translation, validation and adaptation to Italian cultural context of the PSRI. This in order to identify all those problematic situations in which pregnancy has a negative effect on the couple's sex life in quantitative and qualitative terms.

The sample consisted of 37 women. As shown in **Table 2**, the average age of the sample was 32.78 years (SD ± 5.03 , min. 24, max. 40), while the average age of their partners was 35.35 years (SD ± 5.40 , min. 27, max. 50). The sample was equally distributed among the three trimesters of pregnancy, with an average of 26.27 weeks (SD ± 10.32 , min. 10 weeks, max. 40 weeks).

The entirety of our sample declared to be married or cohabitant. 51.4% of the surveyed women has a

Table 1. Description of grouped questions for each domain.

Domains	Questions		
	Before pregnancy	During pregnancy	All
PSRI (specific score)			
Female perception			
Frequency	14a	13, 14b, 14c	13, 14a, 14b, 14c
Desire	21a	21b, 22	21a, 21b, 22
Arousal	18a	18b	18a, 18b
Orgasm	23a	23b	23a, 23b
Satisfaction	15a, 17a	15b, 17b	15a, 15b, 17a, 17b
Dyspareunia	24a	24b	24a, 24b
Intercourse starts	25a	25b	25a, 25b
Female difficulties	19a	19b	19a, 19b
Female perception of partners			
Male sexual satisfaction	16a	16b	16a, 16b
Male sexual difficulties	26a	26b	26a, 26b

The numbers followed by letters are the number of PSRI.

Table 2. Nominal descriptive variables of the sample.

Variables	Mean \pm SD
Maternal age	32.78 \pm 5.03
Paternal age	35.35 \pm 5.40
Gestational age	26.27 \pm 10.32

higher education level, 37.8% has a university degree and only 10.8% has an elementary / medium level of education. The prevailing religion among the sample is Catholicism with a percentage of 83.8%, while the remaining women declared to practice other religions not specified in the questionnaire. The majority of women was found to have a job (78.4%), not smoke, not use alcohol or drugs. Primigravidae women represent 62.2% of the sample, in contrast to 37.8% which is multipara, with two or more children. A high percentage of our sample reported having planned pregnancy (67.4%). 70.3% of the women in the study does not use condoms, among the 29.7% whom does use condoms, only 2.7% of them says they use them frequently. The demographic characteristics of the sample are shown in **Table 3**.

The numerical calculation of the values expressing sexual health's quality, obtained through the use of Likert scale, for the different domains of the PSRI, shows important differences both the pre-conception and gestational periods. As shown in **Table 4**, higher values are observed for all items in pre-pregnancy period, compared to significantly lower values during pregnancy.

The highest difference for the same domain in relation to the period was found in questions concerning orgasm (23a, 23b), female difficulties (19a, 19b), satisfaction (15a, 15b, 17a, 17b), and the female perception of male sexual satisfaction (16a, 16b). These items in fact scored "excellent" on the Likert scale (75-100) for the pre-pregnancy period, reducing during pregnancy to a score reflecting a "bad" sexual health status (25-50).

The scores that did not differ much in both periods considered were identified in the questions concerning sexual desire (21a, 21b, 22). This difference was only 5.04 points, which shows that sexual desire within the couple is not altered, and it remains constant even during pregnancy.

The reduction within the 10 domains was almost equal to about half of the scores obtained in the period before pregnancy. This shows how sexual health deteriorates during pregnancy, in fact the compositive score obtained from the sum of the domains of pre-pregnancy sexual activity was

Table 3. Demographic characteristics of the sample.

Variables	Frequency (%)
Partnership status	
Married/living together	37 (100)
Single	0 (0)
Other	0 (0)
Sociodemographic factors	
Education level	
Basic level	4 (10.8)
High school	19 (51.4)
University	16 (37.8)
Religion	
Catholic	31(83.8)
Protestants/Evangelis	0 (0)
Other	6 (16.2)
Employment status	
Not employed	8 (21.6)
Employed	24 (64.9)
Not currently employed	5 (13.5)
Children	
No	23 (62.2)
Just one	11 (29.7)
Two or more	3 (8.1)
Smoke	
Yes, often	2 (5.4)
Yes, sometimes	5 (13.5)
No	30 (81.1)
Drink alcohol	
Yes, often	0 (0)
Yes, sometimes	8 (21.6)
No	29 (78.4)
Illicit drugs	
Yes, often	0 (0)
Yes, sometimes	0 (0)
No	37 (100)
Planned pregnancy	
Yes	25 (67.6)
No	12 (32.4)
Use of condoms	
No	26 (70.3)
Yes, stopped before pregnancy	10 (27)
Yes, often	1 (2.7)

81.39 (SD \pm 14.05), which corresponds to a state of "excellent" sexual welfare, much higher than the value of the questions concerning pregnancy, which obtained a total score of 51.85 (SD \pm 13.44), just above the limit of definition of "excellent" sexual health. The difference, statistically significant ($p = 0.000$) was 29.54 points (SD \pm 11.11).

Results obtained by using Student t-test for all the domains, always gave a high statistical significance with a P-value < 0.05 , with the exception of ques-

Table 4. Likert scale values for each domain.

Domains	Before pregnancy Likert score \pm SD	During pregnancy Likert score \pm SD	Difference between domains \pm SD	P-value
Frequency	62.16 \pm 24.74	34.23 \pm 26.04	27.92 \pm 23.91	0.000
Desire	56.76 \pm 47.38	51.35 \pm 20.37	5.40 \pm 44.54	0.465
Arousal	71.62 \pm 25.11	40.54 \pm 36.96	31.08 \pm 36.03	0.000
Orgasm	81.08 \pm 29.70	44.59 \pm 38.70	36.48 \pm 45.10	0.000
Satisfaction	84.46 \pm 19.85	41.89 \pm 30.65	42.56 \pm 35.28	0.000
Dyspareunia	97.30 \pm 16.44	67.57 \pm 47.46	29.72 \pm 46.33	0.000
Intercourse starts	90.28 \pm 20.07	68.06 \pm 29.65	22.22 \pm 32.61	0.000
Female difficulties	97.30 \pm 16.44	59.46 \pm 49.77	37.83 \pm 49.16	0.000
Male sexual satisfaction	81.08 \pm 31.95	40.54 \pm 36.96	40.54 \pm 36.96	0.000
Male sexual difficulties	91.89 \pm 27.67	70.27 \pm 46.34	21.62 \pm 41.73	0.003
Compositive score	81.39 \pm 14.05	51.85 \pm 13.44	29,54 \pm 11.11	0.000

Student t-test for paired domains, difference between domains \pm standard deviation, and statistical significance (P-value).

tions concerning sexual desire (21a, 21b, 22) having a significance equal to a P-value of 0.465.

Cronbach's alpha calculated for each item of the questionnaire obtained a value of 0.79. A subsequent calculation, which excluded the demographic description items of the sample (1-12), produced instead a Cronbach's alpha value of 0.78, showing that Italian PSRI has a good internal coherence and reliability.

In addition to having carried out statistical analyses for the validation of the instrument, one of the substantial steps for Italian cultural adaptation was to make linguistic changes. Some terms, after the processes of translation from the original language, and after a consultation among the panel of experts involved in the study, have been replaced by more commonly used words for which there is less embarrassment in Italian culture.

For example, the word "excitement" has been replaced by the word "arousal", in order to reduce any discomfort between the target sample and the operators. From the entire process of validation, translation and adaptation to the Italian language, the final version of the Pregnancy Sexual Response Inventory has been produced, presented in the same format as the original.

DISCUSSION

The results of this study highlight how certain habits and some facets of a couple's sexuality are mu-

tated negatively or are mutated when a pregnancy arrives. It was confirmed what literature points out about pregnancy sexuality, means decrease in frequency of sexual intercourse during the nine months of pregnancy and reduction in performance satisfaction, both from the woman's point of view and from the partner's, and higher female difficulty [7-11]. The causes of this, however, are still being studied in the scientific world today. Moreover, an important aspect that highlighted in this pilot study is how desire in Italian women remains an unaltered parameter during pregnancy. Therefore, although the wish and desire of pregnant couples remains unchanged, there are still some obstacles to which a resolution should be given.

The historical period in which the pilot study takes place and the presence of the COVID-19 pandemic has changed the lifestyle of pregnant women. The pandemic has altered women's daily lives, increasing the presence of psychological problems and reducing their physical activities [34-36], conditions for which their sex life could also have changes.

Italian PSRI obtained, which has good internal consistency and reliability, is an excellent tool to use in clinical practice, both by obstetricians and other health professionals, for a more in-depth investigation of pregnant women's sexual health. It subsequently allows the implementation of all the supporting interventions necessary to resolve these problems, also directing couples to sexologists and other specialists in the field.

The PSRI can also be useful for a possible census of the sexual activities and behaviour of Italian women and couples, in order to be able to operate and intervene in this area in a standardised way throughout the country.

The use of quartiles, using Likert's scale, has made it possible to express in an easy and understandable way the quality level of sexual health of the sample examined. Moreover, the use of a not excessively specific terminology, and the comparison with the sample during the distribution and the compilation of the questionnaire, did not reveal any linguistic difficulty; in fact, no woman sampled found words or questions unclear for comprehension.

The study, carried out in conjunction with the SARS-CoV-2 health emergency, has suffered from some limitations; in fact, the sample examined could not benefit from normal interaction with the midwife of reference, as the use of containment measures has somehow influenced their total freedom of comparison. The number of samples, despite being pre-set according to the guidelines consulted for the validation of scientific instruments, was limited due to the large number of pregnant women with obstetrical pathologies, an exclusion criteria of the study, at the Department of Obstetrics and Gynaecology, Fondazione Policlinico Universitario "A. Gemelli" in Rome, sampling setting. The retrospection of some questions in the questionnaire may represent a bias for this study. Investigating the habits and the state of sexual welfare before pregnancy may, in fact, increase the risk of compromising the veracity of the answers, especially in women who find themselves in the third trimester of pregnancy, as they are further away from the pre-gestational time.

Cronbach's alpha was found to have a not excessively high value (P-value = 0.78), for which an in-depth examination and possible modification of the items analysed is recommended. The alteration of this parameter may also have been caused by the lack of response, by a small percentage of the sample, to question number 20. Lastly, the Italian translation is added to the other pre-existing versions of the PSRI, increasing the possibility of its use and diffusion at an international level.

CONCLUSIONS

This study led to a drawing up of an Italian language version of the Pregnancy Sexual Invento-

ry Response, which is the only questionnaire designed to assess the quality of sexual life, targeted and dedicated to pregnant women. By comparing two different periods (before and during pregnancy), it is an excellent tool for identifying changes or alterations in sexuality in couples' lives.

Therefore, the Italian PSRI expands the literature of our country on a subject not widely inquired yet, while also embracing the world of obstetrics. It is therefore more effective in identifying sexual problems during pregnancy and their causes, thus allowing operators to apply targeted and multidisciplinary assistance towards the needs of couples, with the ultimate aim of improving their welfare, and in particular their sexual health.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contributions

M.L.R., G.A., A.L.: Conceptualization. G.C., M.D.: Data curation. M.L.R., A.G., G.C.: Formal analysis. M.L.R., G.C., M.D., G.A.: Investigation. M.L.R., G.C., G.A.: Methodology. M.L.R., G.C., G.A.: Project administration. M.L.R., A.L.: Supervision. M.L.R., G.C., M.D., G.A.: Visualization. M.L.R., G.C., G.A.: Writing – original draft. M.L.R.: Writing – review & editing.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

The validation and adaptation study of the tool was conducted in full compliance with the latest revision of the Helsinki declaration. This study obtained the authorization from the ethics committee of the Fondazione Policlinico Agostino Gemelli in Rome on 14 October 2020, which was entrusted with the protocol number ID 3518.

Informed consent

All the information provided for the purpose of the investigation are strictly confidential in accordance with the GDPR 679/2016 and the privacy decree Legislative Decree 101/2018.

Data sharing

Data are available under reasonable request to the corresponding author.

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