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Assessment of the psychometric properties of the Italian version of the revised impact of miscarriage scale (RIMS): a validity and reliability study

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Abstract

Background Miscarriage is a traumatic life event that involves over forty thousand Italian women every year. Women affected by this loss can have long-term psychological consequences. For this reason, it is paramount to identify women at risk of developing such complications to ensure they receive proper support. The aim of this study is to perform a translation into Italian and a validation of the Revised Impact of Miscarriage Scale (RIMS), which is a valuable support for healthcare professionals to assess women after a miscarriage.

Methods Double-translation technique was performed. A sample of 543 women completed the survey for the validation process which included RIMS, the Perinatal Grief Scale (PGS) and NSESSS. These last two instruments are usually used to assess the impact of perinatal loss on women's life.

Results The Italian version of RIMS (RIMS-IT) has good internal consistency (Cronbach's alpha value 0,89). Factor analysis was conducted to confirm the construct validity and three factors were extracted. They reflected the factorial analysis of the original version. Scores of RIMS, PGS, and NSESSS were strongly correlated.

Conclusions RIMS-IT can be a valuable support for clinicians and researchers to identify women at risk of developing psychiatric symptoms and to analyse factors involved in the onset of these complications.

Keywords Miscarriage, Midwives, Bereavement, Screening

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Introduction

The Royal College of Obstetricians and Gynaecologists defines miscarriage as "the spontaneous loss of pregnancy before the foetus reaches viability" and this term usually includes all pregnancy losses before 24 weeks of gestation [1]. A recent paper published in a series of The Lancet entitled "Miscarriage matters" highlights that the risk of miscarriage is 15.3% in high-income countries [2]. In Italy, any loss that occurs until 25 weeks and 5 days of gestation is deemed as a miscarriage by law [3]. Italian data for 2020 showed that over forty thousand miscarriages took place every year [4]. However, this phenomenon is underestimated since this figure only takes into account women discharged from either public or private healthcare institutions and doesn't consider those that weren't admitted to a hospital.

Miscarriage is a traumatic life event that can lead to long-term psychological consequences such as complicated grief [5], post-traumatic stress, anxiety, depression, and carries an increased risk of suicide [2]. Sometimes, these sequelae might be unrecognised by health-care professionals (HCPs) and patients' relatives, since miscarriage is considered by society as unimportant and something to hide [2, 6]. Although miscarriage is a healthcare matter of global interest due to its high frequency, it continues to remain a taboo worldwide, and it's linked to stigma and shame [7]. This taboo leads to a lack of social support, which in turn is known to be a predictor for the development of complicated grief [2, 5]. Complicated grief was identified as a condition deserving further studies in the fifth edition of the Diagnostic and Statistical Manual of mental disorders (DSM-5) [8]. Nine years later, the text revision of the DSM-5 (DSM-5-TR) includes "Prolonged grief disorder" [9], giving formal recognition to a condition long described by literature.

For all the aforementioned reasons, it is paramount to have proper instruments to establish the psychological impact of a miscarriage. As far as we know, the Impact of Miscarriage Scale (IMS), which was recently revised [10], is the only specific scale that evaluates the experience of miscarriage and not just grief as the Miscarriage Grief Inventory [11]. The IMS was specifically developed to investigate the multifaceted impact of miscarriage, focusing on the individual's perception of the event and its broader psychological, social, and emotional effects. In contrast, the MGI is primarily focused on measuring grief responses associated with miscarriage, providing a narrower scope centred on the bereavement aspect. Other commonly used scales are the Perinatal Grief Scale (PGS) and the National Stressful Events Survey PTSD Short Scale (NSESSS). The PGS is available in Italian and has been validated for this population, thus ensuring its reliability in the Italian context [12, 13]. The NSESSS assesses the severity of posttraumatic stress symptoms after extremely stressful events, including perinatal loss, but it is not specific to miscarriage [14, 15]. Both tools are valuable for studying perinatal bereavement, but they do not provide the same level of specificity as the IMS, which targets the unique experience of miscarriage.

Literature about the individual experience of miscarriage and the coping strategy is very poor. Moreover, it is well known that it's very important to identify women at risk of psychological distress and their needs to tailor a proper care [16]. Therefore, it could be useful, in both clinical settings and the research field, to have an instrument that aims to evaluate the experience of miscarriage.

Methods

The purpose of this paper is to create an Italian version of the Revised Impact of Miscarriage Scale (RIMS). The process consisted of an Italian translation, cultural adaptation, and validation in a group of Italian women.

Translation process

This work was carried out by a team of researchers from the University of Florence and University of Milano-Bicocca. The research group has previous experience in validation of scales applied in the obstetric field [13, 17–19]. After receiving consent from the developers of RIMS, the scale was translated from English to Italian following the methodology reported in "Translation and Cultural Adaptation of Patient Reported Outcomes Measures - Principles of Good Practice" [20]. Briefly, the original English version was independently translated into Italian by three English speaking healthcare professionals. Results were then harmonised by an independent English native speaker who had not been involved in the forward translations. After that, three Italian translators back-translated the scale into English without having seen the original version. The original version and the back-translated version of the RIMS were then compared. The back-translation process was carefully managed to maintain the accuracy and meaning of the original items. We engaged bilingual experts to perform the back-translation and compare it with the original scale to ensure consistency. Any discrepancies identified during this process were addressed through iterative revisions to achieve linguistic equivalence. A panel of 5 Italian experienced midwives tailored the literally translated version of the tool to Italian culture. This involved not only translating the text but also adapting examples and references to be relevant to Italian experiences of miscarriage. We consulted with cultural experts and conducted pre-testing with a sample of 5 Italian-speaking participants to ensure that the scale was understood as intended. Finally, the definitive version was corrected and modified in order to resolve any remaining spelling, diacritical, grammatical

Table 1 Demographic and obstetric characteristics of the sample

	No.	%
Age classes		
20–33	205	37.8%
34–38	184	33.9%
39–49	154	28.4%
Highest level of education		
Lower secondary education	16	2.9%
Upper secondary education	151	27.8%
First stage of tertiary education	110	20.3%
Second stage of tertiary education	136	25.0%
Master or Doctorate	130	23.9%
Body Mass Index		
Underweight	29	5.3%
Healthy weight	330	60.8%
Overweight	127	23.4%
Obesity	57	10.5%
Elapsed months		
< 3	117	21.5%
3–6	99	18.2%
6–12	158	29.1%
12–24	122	22.5%
24–36	47	8.7%
Previous pregnancy losses (n)		
0	146	26.9%
1–2	307	56.5%
> 2	90	16.6%
Assisted Reproductive Technologies		
No	499	91.9%
Yes	44	8.1%
Currently pregnant		
No	472	86.9%
Yes	71	13.1%
Total	**543**	**100.0%**

or other mistakes, and to make the interpretation of the scores and the final statistics easier.

Validation process

Participants

All participants were Italian-speaking and reading women who had experienced a miscarriage in the 36 months before answering the questionnaire. A 36-month time frame was chosen to align with clinical and research practices, which often use extended periods to assess the impact of significant life events on psychological well-being. This approach allows for a more thorough understanding of the long-term consequences of pregnancy loss and facilitates standardised comparisons with other studies and clinical assessments.

Inclusion criteria included miscarriage within the 180th day of gestation (the limit set by Italian law that differentiates miscarriage from stillbirth).

The survey was distributed via CiaoLapo Foundation, an Italian charity for perinatal loss support, using existing networks and support groups across Italy. The network of CiaoLapo Foundation comprises women and couples affected by perinatal loss, as well as numerous associations, organisations and groups dealing with healthy pregnancy and perinatal health. The survey was disseminated through various channels, including online forums, social media platforms, and newsletters, reaching a broad audience within the community. Participation was entirely voluntary, and individuals self-selected to complete the survey without any direct solicitation or compensation.

Consent was provided at the start of the survey once participants had read the participant information and met the eligibility criteria. The survey was launched, and data collected from April to July 2022.

A member of the research team was available to answer any queries, to provide more detailed information on the study, and to discuss potential participation. The study was reviewed and approved by an ethics committee, which ensured that all procedures complied with ethical standards for research involving human participants.

Instruments

Revised Impact of Miscarriage Scale (RIMS) [10]: includes 16 questions divided into three factors, 'Isolation and guilt', 'Loss of baby' and 'Devastating event'. The 'Isolation and guilt' dimension assesses the feelings of isolation and self-blame that individuals may experience following a miscarriage. It captures the emotional burden related to personal feelings of inadequacy and separation from other (e.i. Item *"I often feel that others cannot understand the depth of my pain"*). The "Loss of baby" dimension evaluates the emotional impact of the loss of the baby, focusing on the personal sense of loss and mourning associated with the miscarriage (e.i. Item *"I deeply mourn the loss of the baby I was expecting"*). The "Devastating event" dimension measures the perceived severity of the miscarriage as a life-altering event, including the distress and disruption it causes to the individual's life (e.i. Item *"This loss has been one of the most devastating events of my life"*). The study subjects answered all statements in RIMS, responses and scores were (1) 'definitely true for me', (2) 'quite true for me', (3) 'barely true -for me' and (4) 'definitely not true for me', with a possible total score of 64. All items were analysed by reverse coding, higher scores represented higher significance and meaning. None of the questions were open ended.

Perinatal Grief Scale (PGS) [12]: is a simple and complete instrument used to assess the grief after perinatal loss. The Italian version of PGS has good validity and reliability and is an important instrument of first prevention, able to identify women at risk of developing complicated

forms of grief and therefore needing specific support. The scale consisted of 33 items of Likert type whose answers vary from 1 (strongly agree) to 5 (strongly disagree). The PGS presents three subscales: 'active grief' (AG), 'difficulty in coping' (DC) and 'despair' (D).

National Stressful Events Survey PTSD Short Scale (NSESSS) [14]: is a 9-item measure that assesses the severity of posttraumatic stress disorder in individuals age 18 and older following an extremely stressful event or experience. The measure was designed to be completed by an individual upon receiving a diagnosis of posttraumatic stress disorder (or clinically significant posttraumatic stress disorder symptoms) and thereafter, prior to follow-up visits with the clinician. Each item asks the individual receiving care to rate the severity of his or her posttraumatic stress disorder during the past 7 days. Scoring and Interpretation Each item on the measure is rated on a 5-point scale (0 = Not at all; 1 = A little bit; 2 = Moderately; 3 = Quite a bit, and 4 = Extremely). The total score can range from 0 to 36 with higher scores indicating greater severity of posttraumatic stress disorder.

Data and statistical analysis

Survey responses were downloaded from the online survey tool Qualtrics and imported into Excel for data management. Incomplete records were excluded, and data was imported into Stata/BE 17.0 (StataCorp) for statistical analysis. Descriptive statistics were used to analyse quantitative data. Categorical data were reported as frequencies and percentages and compared using the chi-squared test, whereas continuous data were reported as mean values with standard deviations (SD) or as median [quartiles] and compared using t-test or Kruskall Wallis and Mann Whitney test. All results were considered to be statistically significant at $p < 0.05$.

Cronbach's alpha (and related 95% confidence interval, CI) was calculated for all subscales. An alpha coefficient $\alpha \geq 0.70$ was considered as good internal consistency reliability. Cohen's kappa was calculated to evaluate concordance. Kappa value, according to Landis and Koch, was categorised as fair (0.2–0.4), moderate (0.4–0.6), good (0.6–0.8) and very good (0.8–1).

Principal Component Analysis (PCA) with varimax rotation was conducted to examine the construct validity of the 16-item RIMS-IT. This method was used to reduce the dimensionality of the data while retaining as much variability as possible. The analysis aimed to identify the main components underlying the responses, facilitating a clear understanding of the structure of the scale. Component loadings were then analysed to determine the association of each item with the extracted components, ensuring consistency with the original subscales.

Table 2 Factor analysis of RIMS-IT. In bold items corresponding to the proposed subscales in the english version

Item	Component 1	Component 2	Component 3	Unexplained
rims1	0.2354	**0.2738**	0.2479	0.4242
rims2	0.2139	***0.1854**	*0.3645	0.4624
rims3	0.2132	**0.3631**	0.1257	0.4472
rims4	0.2189	**0.2535**	0.2237	0.5074
rims5	0.2073	**0.3366**	0.0314	0.517
rims6	0.2551	**0.2630**	-0.0060	0.4569
rims7	0.2534	-0.3594	**0.2223**	0.2857
rims8	0.1957	-0.4483	**0.2311**	0.316
rims9	0.2110	-0.3008	**0.2695**	0.4506
rims10	*0.2804	-0.1824	***0.1230**	0.4146
rims11	*0.3009	-0.1907	***0.0778**	0.3451
rims12	**0.2831**	-0.0443	-0.3527	0.3125
rims13	**0.2380**	-0.0868	-0.4360	0.3631
rims14	**0.2980**	-0.0679	-0.3670	0.2379
rims15	**0.3016**	0.0310	-0.2342	0.34
rims16	**0.2545**	0.0823	-0.1955	0.5202
Subscale	**Devastating Event**	**Isolation / Guilt**	**Loss of the baby**	

* indicates items conflicting between two subscales

Statistics were performed with Stata/BR 18.0 (StataCorp) whereas maps and graphs were plotted using Tableau Desktop 2024.3 (Tableau Software, LLC).

Results

Participant characteristics

A total of 543 women completed the survey, with participants from all Italian regions. The majority of respondents (313, 57.7%) were from Northern Italy, followed by 135 (24.8%) from Central Italy and 95 (17.5%) from Southern Italy and the Islands, reflecting the general demographic distribution of the Italian population. Table 1 shows demographic and obstetric characteristics of the sample.

Age of participants ranged from 22 to 48 (mean 35.3, SD 4.7). All participants were women who had experienced a perinatal loss during the previous 12 months; 146 of them (26.9%) had lost a first pregnancy to miscarriage, while 73.1% had already experienced one or more pregnancy losses during their life. The average of the elapsed months since the last miscarriage was 10.1 (SD 8.4). The median week of the miscarriage was 9 (quartiles [7;12], mean 10.3, SD 4.6); distribution of the tertiles of gestational weeks at loss is reported in Fig. 1.

Psychometric scales

Results of psychometric scales are reported in Fig. 2, and Fig. 3 shows the geographical distribution of PGS and RIMS total scores (panel A) and the correlation.

Based on the distribution of total scores, our sample showed higher scores for PGS and RIMS compared to

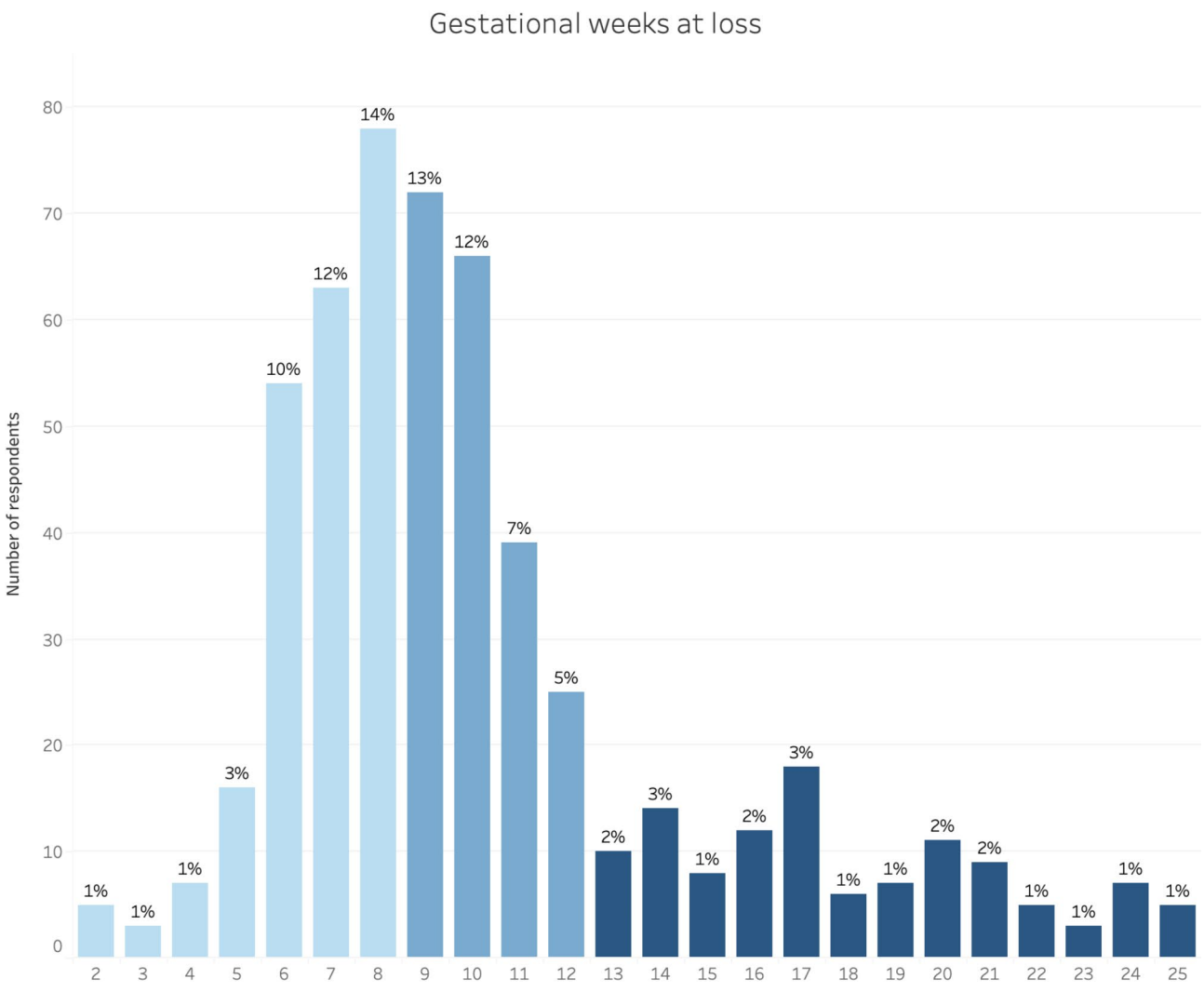

Fig. 1 Distribution of the tertiles of gestational weeks at loss

NSESSS. 61% of the subjects who completed RIMS are represented in the last three columns of the bar chart (50% for PGS and 25.7% for NSESSS). Additionally, only one subject who answered NSESSS is represented in the final column.

Factor analysis was conducted to confirm the construct validity of the 16-items RIMS-IT. The first three components had eigenvalues of 6.41, 1.82, and 1.37, respectively, collectively explaining 60% of the total variance. The first component explained 40.0% of the variance, the second 11.4%, and the third 8.6%. Results reported in Table 2 broadly reflect the factorial analysis of the original English version. While most items aligned with the original subscales, three items showed higher loadings on different components, suggesting a slightly different structure in the Italian context. Items were nevertheless assigned to the same three subscales as the original English version for consistency.

Internal consistency of the instrument was measured by means of Cronbach's alpha for the total score and for each of the three subscales: RIMS tot 0.89, RIMS Isolation/Guilt 0.80, RIMS Loss of the Baby 0.83, RIMS Devastating Event 0.84.

Total and subscale scores of RIMS, PGS and NSESS were strongly correlated to each other; correlation graphs and coefficients are reported in Fig. 3 and in Table 3.

Discussion

The present study is the first attempt to create an Italian-validated version of the Revised Impact of Miscarriage Scale. One translation and validation of this tool into Swedish [21], performed using the double-translation technique, has already been published in literature. The main challenge of the translation process was to adapt the tool to the Italian cultural context, while taking into account grammatical syntax. To better overcome these cultural differences, a group of senior Italian midwives

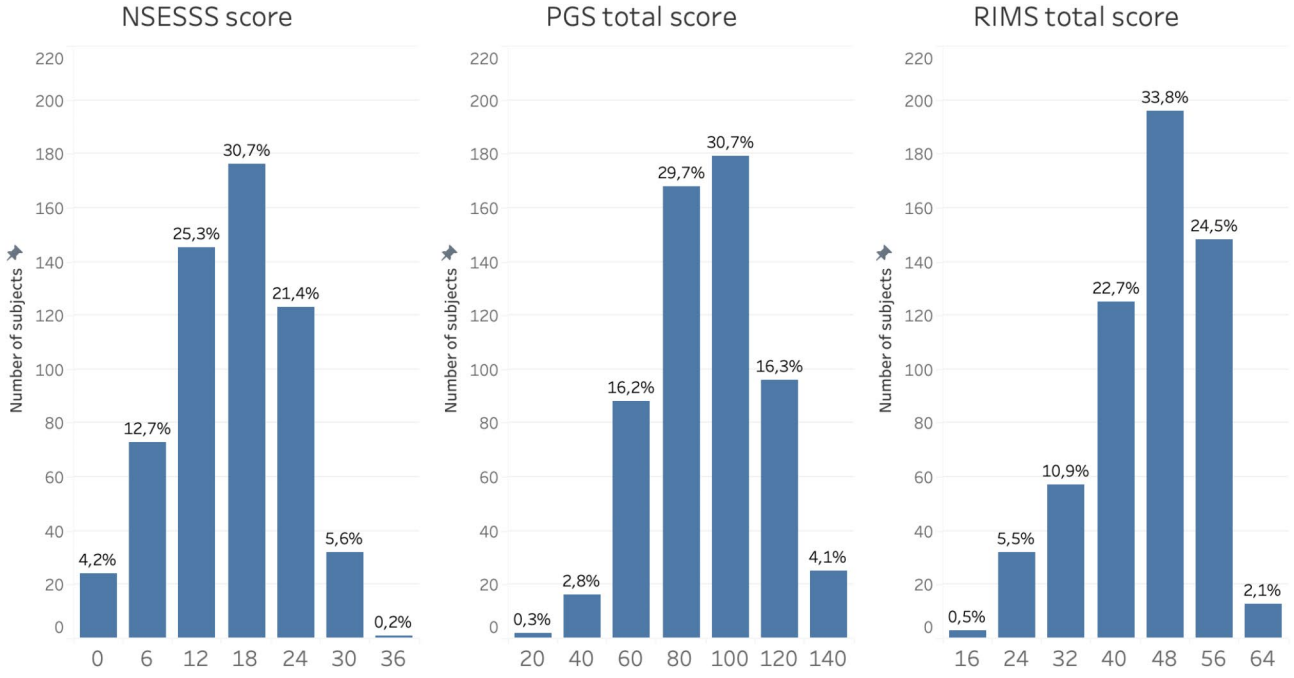

Fig. 2 Distribution of psychometric tests total scores

revised and tailored the RIMS to the Italian population after the back-translation process. Our sample appears to resemble the general population of women who have experienced a miscarriage [22].

According to the literature, the internal consistency of the total score and for each of the three subscales is good [23, 24]. The confirmatory factor analysis revealed an excellent fit to the tri-dimensional model of the original version. Moreover, the three factors extracted explained 60% of the variance, akin to the English version [10]. Although the items were assigned to the same subscales, three of them were more fitting in a different one. In particular "I feel guilt about my miscarriage" was more suited with "Loss of the baby" subscale than "Isolation/Guilt"; "I dwell on the fact that my child will only exist in my memory" and "Through miscarriage, I feel I lost a part of myself" were more suited with "Devastating Event" subscale than "Loss of the baby". However, we decided to assign items to the same subscales of the original version for two reasons: the first one is that this paper represents just the first attempt to validate RIMS for Italian population and further research is needed to confirm our results, the second one is that the "Loss of baby" subscale would only have three items impairing its meaning. Our findings demonstrate high internal consistency reliability, with Cronbach's alpha values indicating that the scale reliably measures the intended constructs across the sample. We compared the Italian version of RIMS (RIMS-IT) with PGS and NSESSS which are two instruments usually used to assess grief and post-traumatic stress symptoms after a perinatal loss. Total and subscales scores of RIMS-IT were strongly correlated to those of PGS and NSESSS.

Therefore, RIMS-IT could be a useful instrument for midwives to screen women after miscarriage and to refer those with a high score to a formal assessment with a mental health professional. Existing instruments, such as the PGS, assume that women are in mourning after

Table 3 Correlation analysis of psychometric tests. Table shows coefficients of correlation; all significant at $p < 0.001$

		NSESSS	PGS				RIMS		
			Total score	Active Grief	Difficulty Coping	Depers.	Total score	Isolation Guilt	Loss of the baby
PGS	Total score	0.626							
	Active Grief	0.524	0.902						
	Difficulty Coping	0.625	0.935	0.764					
	Depersonalization	0.582	0.933	0.754	0.822				
RIMS	Total score	0.505	0.724	0.737	0.644	0.632			
	Isolation Gulit	0.455	0.689	0.615	0.646	0.647	0.833		
	Loss of the baby	0.332	0.508	0.600	0.408	0.411	0.812	0.453	
	Devastating event	0.468	0.580	0.609	0.523	0.483	0.834	0.556	0.575

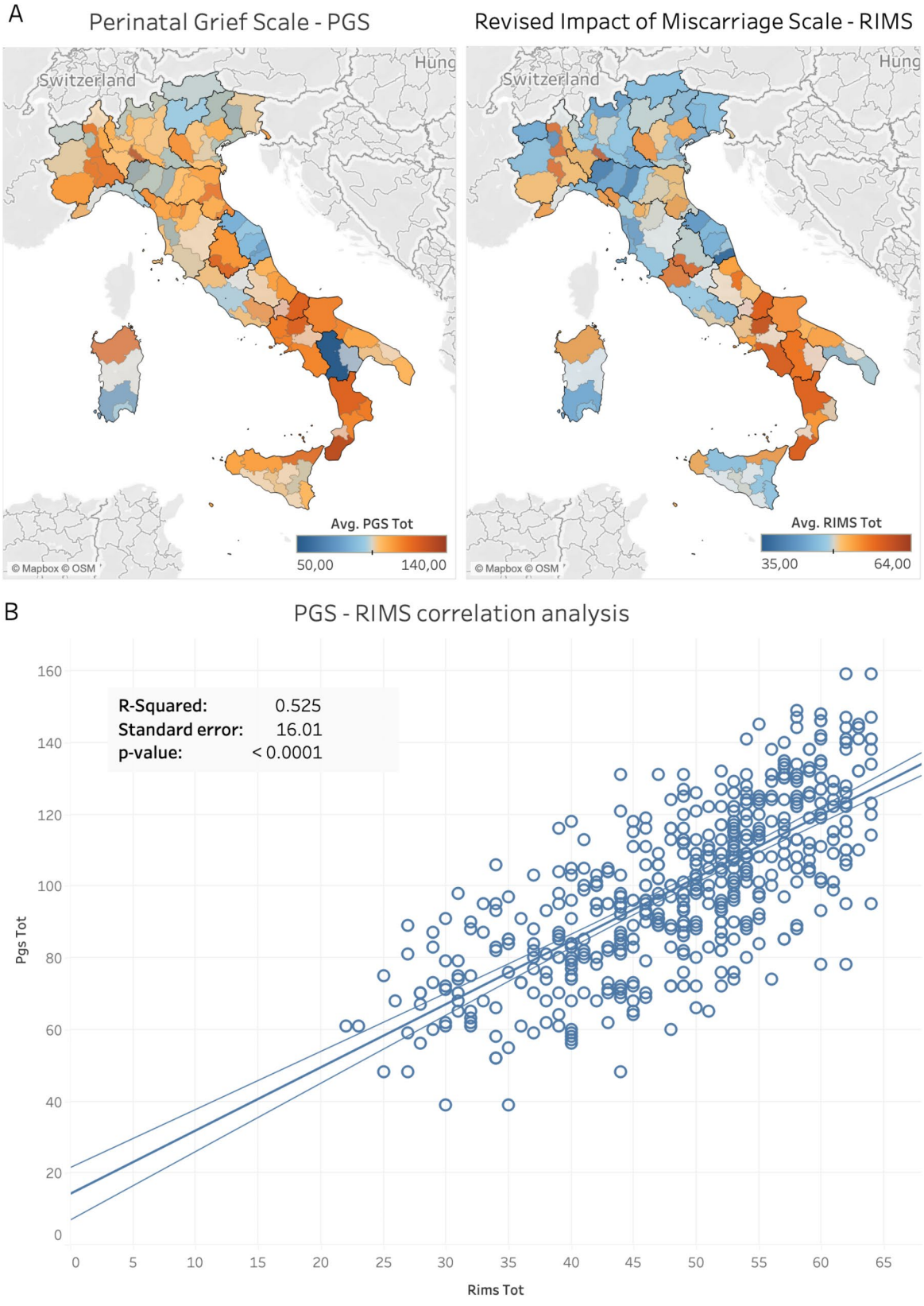

Fig. 3 Geographical map and correlation of psychometric scales

a perinatal loss. However, not all women after a miscarriage have this feeling or are aware of it, so RIMS-IT could be more suitable for this population. Further research is needed to identify the psychological constructs related to RIMS subscales. In particular, only the dimension of "Guilt/Isolation", which indeed are very different concepts, could be considered a psychological construct; while "Loss of baby" and "Devastating event" do not refer to any complex psychological concept.

Moreover, our data showed higher distribution of subjects in the last three columns for PGS and RIMS compared to NSESSS. This difference reflects the specificity of the scales in assessing subjects' experience about loss: PGS and RIMS are specific tools to assess emotions and thoughts after loss while NSESSS reflects PTSD symptoms. In line with the existing literature, our results underlined that around one quarter of women developed PTSD symptoms 6, confirming that NSESSS identified only cases where loss had a severe impact on women's mental health. These data support the pivotal role of RIMS-IT as a specific tool to assess the psychological impact of early losses avoiding an underestimation of symptoms. These results underscore the effectiveness of RIMS as a screening tool to identify women in need of additional care at an early stage, enabling the development of personalized, women-centered support tailored to their specific needs.

Leaving mental health issues unidentified and untreated after a miscarriage could increase the risk of psychiatric sequelae, so healthcare professionals should routinely screen all women after loss [25] in order to refer them to additional and specialised care [26]. The World Health Organisation (WHO) includes mental health screening after childbirth in the "routine care" section underlining that it should be guaranteed to all women [26]. Moreover, the International Consortium for Health Outcomes Measurement (ICHOM) recommends the evaluation of the outcomes that matter most to patients experiencing pregnancy to improve efficiency and effectiveness of clinical care [27]. Although ICHOM only includes stillbirth as a survival-related outcome, we argue that this evaluation should be extended to miscarriage given its impact on public health.

Strength and limitation

The main strength of the validation process is the large sample which is spread over all the Italian territory.

However, this paper has some limitations. One significant limitation is the absence of fathers in the sample, whereas the original version of RIMS was validated for both mothers and fathers.

Moreover, the majority of the sample already had one or more previous perinatal losses before or after the miscarriage assessed by RIMS. We expected such a sample composition as the presence of multiple perinatal losses can lead women to seek more information and support through CiaoLapo and its network. While no statistically significant difference was found between women with single and multiple losses, nor any different result was obtained when restricting the analysis to women with a single loss, it is important to note that our study was not specifically powered to detect these differences. Therefore, caution is advised in interpreting these findings.

It is also important to reflect on the selectivity of the population in which the survey was conducted. The CiaoLapo network primarily reaches women who are actively seeking support and information about perinatal loss, which may result in a sample that is more engaged and possibly more affected by their experiences compared to the general population.

Conclusions

The Italian version of RIMS could be a useful tool for screening to identify women at risk of developing a mental health disorder after a miscarriage. Formal assessment and support should be offered to these women to avoid long-term psychological consequences.

Concerning further research, the validation of RIMS-IT for fathers should be a priority. The impact of miscarriage on men's life is often underestimated and this tool could be a useful instrument to assess their wellbeing and offer them proper care.

In the end, RIMS-IT could be a valuable support for researchers to analyse factors which play an important role to promote the onset of psychiatric symptoms after a miscarriage.

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Author contributions

AN, SF, AV and CR led this research including proposal write up and designed the instrument. CR, AV, RB collected the data; AV and RB analysed the data; AN, SF, LM, AV and CR discussed data and wrote the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets generated and/or analysed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was undertaken in accordance with ethical standards from The Code of Ethics of the World American Association (Declaration of Helsinki, 1964) and its later amendments. Ethical approval was obtained from the University of Milano Bicocca Ethics Committee prior to commencing the study

(Approval number: 0021150/22, approval data: 10/03/2022). Every participant provided at the start of the survey his consent after reading the participant information and meeting the eligibility criteria.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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