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Minerva Obstetrics and Gynecology 2024 April;76(2):118-26
DOI: 10.23736/S2724-606X.23.05375-7

ORIGINAL ARTICLE

Medically assisted reproduction in Italy, 2020 data from the Italian MAR Register

Giulia SCARAVELLI, Roberto DE LUCA, Roberta SPOLETINI, Lucia SPEZIALE, Fabiola FEDELE, Simone BOLLI, Monica MAZZOLA, Anna BERTINI, Cinzia DI MONTE, Vincenzo VIGILIANO *

Italian Medically Assisted Reproduction Register, Italian National Institute of Health, Rome, Italy

*Corresponding author: Vincenzo Vigiliano, Italian Medically Assisted Reproduction Register, Italian National Institute of Health, Rome, Italy. E-mail: vincenzo.vigiliano@ss.it

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ABSTRACT

BACKGROUND: The Italian Medically Assisted Reproduction (MAR) Register (ItMARR) was established by the Decree of the Minister of Health issued on October 7th, 2005. ItMARR has a crucial role in clearly and publicly disseminating epidemiological information on the MAR activities and outcomes.
METHODS: ItMARR data is collected in aggregate form and is mandatory as set out in Law 40/2004. The aim of this article is to make a snapshot of the authorized centers that perform IUI and ART in Italy. Data used in this article refer to MAR treatments started between January 1st and December 31st, 2020.
RESULTS: MAR techniques were performed by 332 centers. In total, 67,927 ART cycles and 12,171 IUI cycles were performed in 2020. Gametes donation cycles represent 12.9% of ART activity and 4.0% of IUI. ART cycles performed per million women of childbearing age was 6525. In 2020, 2.5% of births in the general population in Italy were a result of application of ART techniques. MAR activity in 2020, has been heavily reduced by the limitations to reproductive treatment due to SARS-CoV-2 pandemic. Pregnancy rates per transfers were 26.7% with fresh techniques, 32.6% with FER, 25.7% with FO, 38.0% with OD and 39.1% with SD. There were fewer multiple deliveries than the previous year.
CONCLUSIONS: The ItMARR, has become a great asset in the reproductive health scenario promoting a better MAR information dissemination. ItMARR is working on the implementation towards a "cycle-by-cycle" data collection system. This will bring the Italian monitoring system in line with others European countries.

(*Cite this article as:* Scaravelli G, De Luca R, Spoletini R, Speziale L, Fedele F, Bolli S, *et al*. Medically assisted reproduction in Italy, 2020 data from the Italian MAR Register. Minerva Obstet Gynecol 2024;76:118-26. DOI: 10.23736/S2724-606X.23.05375-7)

KEY WORDS: Reproductive techniques; Directed tissue donation; Pregnancy; Live birth.

In Italy, the law 40/2004 (Gazzetta Ufficiale N. 45, Feb. 24th, 2004) established the Italian MAR Register (ItMARR) at the National Health Institute and regulates MAR techniques.[1] The ItMARR was established by a Decree of the Minister of Health issued on October 7th, 2005 (Gazzetta Ufficiale N. 282, Dec. 3rd, 2005)[2] at the Istituto Superiore di Sanità, in implementation of the provisions of Article 11 paragraph 1 of Law 40/2004.

Law 40/2004 was particularly restrictive and has since then been amended by four Italian Constitutional Court sentences: in May 2009 the sentence n. 151 abolished the ban on the

production of more than three embryos and the obligation to contemporarily implant all of the embryos produced (Gazzetta Ufficiale 13/05/2009 n. 19);[3] in June 2014, the sentence n. 162 abolished the ban on gamete donation (Gazzetta Ufficiale 18/06/2014 n. 26);[4] in June 2015, the sentence n. 96 abolished the prohibition of access to ART techniques to fertile couples with transmissible genetic diseases in order to perform preimplantation genetic testing (PGT) (Gazzetta Ufficiale 10/06/2015 n. 23);[5] and in November 2015, the sentence n. 229 abolished the ban on embryo selection to avoid the implantation of pathological embryos (Gazzetta Ufficiale 18/11/2015 n. 46).[6]

Presently, MAR techniques performed in Italy include in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), frozen embryo replacement (FER), frozen/warm oocyte cycle (FO), preimplantation genetic testing (PGT), oocyte donation (OD), semen donation (SD), double donation (DD), and intrauterine insemination using either partner (IUI-H) or donor semen (IUI-D). Cycles performed with donated gametes include both transfers performed with fresh embryos and those performed with frozen/thawed embryos.

Reports on previous data collections are available on the ItMARR website (https://www.iss.it/rpma).

The ItMARR's goals are:

• to perform censuses on facilities authorized to apply MAR techniques in Italy, in collaboration with the Italian regional authorities;

• to prepare a report for the Minister of Health each year by the 28th of February. With this report, the Minister of Health presents data on MAR techniques in Italy to parliament to evaluate the global application of law 40/2004;

• to record data on the accessibility, effectiveness, and safety of MAR techniques performed in Italy and their outcomes, including pregnancies and perinatal outcomes;

• to evaluate trends in the application of MAR procedures and their outcomes;

• to promote research and studies in collaboration with the scientific society of reproductive medicine.

The ItMARR also has a crucial role in clearly and publicly disseminating information on the centers' activities and the outcomes of the techniques applied. Moreover, the Register establishes some key performance indicators (KPI) to evaluate each center's activity. KPIs are based on important aspects of clinical and laboratory activity. Each center has the possibility to access only its personal data and could compare them to the national average for any KPI.

The ItMARR is formally linked to the European IVF Monitoring Consortium (EIM) Register of Assisted Reproductive Techniques (https://www.eshre.eu/eim), which collects data from the Registers of European countries. Through the EIM, data from the ItMARR flow to the International Committee for Monitoring Assisted Reproductive Technologies (ICMART) World Register (https://www.icmartivf.org).

The aim of this article is to provide a snapshot of the authorized centers that perform IUI and ART in Italy and to highlight some criticisms of MAR availability and application in our country.

Materials and methods

This article refers to the 16th data collection of the Italian MAR register of the Medically Assisted Reproductive (MAR) activity performed in Italy in 2020.[7]

We evaluated the data from 332 licensed MAR centers, including 197 ART clinics and 135 IUI labs. The data in this article refer to treatments started between January 1st, 2020, and December 31st, 2020.

The ItMARR has collected these data in aggregate. All centers are obliged to provide data as per Law 40/2004. Centers are authorized to carry out MAR procedures by their regional local authorities, and then the centers apply to the ItMARR for registration. The ItMARR verifies the suitability and eligibility of then applications, and then the centers are formally enrolled in the Register and receive an identification code and a password to access their personal area on the ItMARR website. Registered centers enter data twice a year on a dedicated website in two different time frames by filling out seven different forms online. They first send data concerning their activity up to the point where pregnancies

are achieved, and later the data concerning the follow-up of the obtained pregnancies.

Of the seven forms, there is one regarding ART techniques using couple's gametes; one for ART cycles in which PGT is applied; three for techniques with donated gametes (OD, SD, DD); and two for IUI-H and IUI-D techniques.

The fields in each form include strict checks for the suitability and consistency of the data entered by each center.

In the analysis of ART donation cycles, activity and results of double donation (DD) are combined with those of oocyte donations (OD). Data on PGT activity refer to tests performed on embryos created as a result of the application of fresh techniques (IVF and ICSI). PGT cycles are already calculated in the total number of initiated ART cycles. The terminology used by ItMARR refers to the definitions contained in The International Glossary on Infertility and Fertility Care, 2017.[8]

Statistical analysis

Data are presented in absolute numbers and percentages according to the type of applied techniques and to patient age groups. When necessary, stratification is performed according to the center setting (private, public, or private center affiliated with the national health system), and to the size of the centers, meaning the quantity of annual activity performed. Categorical data was compared using the Chi-square Test. Differences with P values <0.05 were considered significant and those with P values <0.01 considered highly significant. All statistical analyses were performed using IBM SPSS Statistics v. 28 (IBM Corporation, Armonk, NY, USA).

Results

MAR accessibility

Of the 332 MAR centers that held authorization in 2020, 12 (6.1%) ART clinics and 38 (28.1%) IUI labs did not carry out any activity. The analysis was therefore performed on 282 MAR centers (185 ART clinics and 97 IUI labs).

These 185 centers performed 67,927 ART cycles in 2020. Fifty-seven percent of the cycles performed were by fresh techniques (7% IVF and 50% ICSI), 28.4% were FER techniques, and 12.9% were performed with gamete donation. Most of the ART activity (66.4% of cycles) was performed in only five regions: Lombardy (22.7%), Tuscany (13.7%), Lazio (11.9%), Campania (9.7%), and Emilia Romagna (8.5%). When considering only gamete donation cycles, 51% of the activity was performed in three regions: Tuscany (20.9%), Lazio (17.2%), and Emilia Romagna (12.8%) (Supplementary Digital Material 1: Supplementary Table I).

The National Health System (NHS) paid for 57% of all ART cycles in Italy. There is a large difference between the northern counties where, on average, 72.4% of the activity is covered by NHS (95% in Lombardy), and the south of Italy, where on average only 23% of ART procedures are paid for by the NHS. The proportion of public activity was higher until 2019, as in 2020 the spread of SARS-CoV-2 resulted in a massive reduction in the number of cycles performed in Italy (-17.8%) especially in the centers of Northern Italy (-30.0%) and in the public centers (-29.2%), as the restrictions applied to health treatments in this area were particularly severe.[9] We also ob-

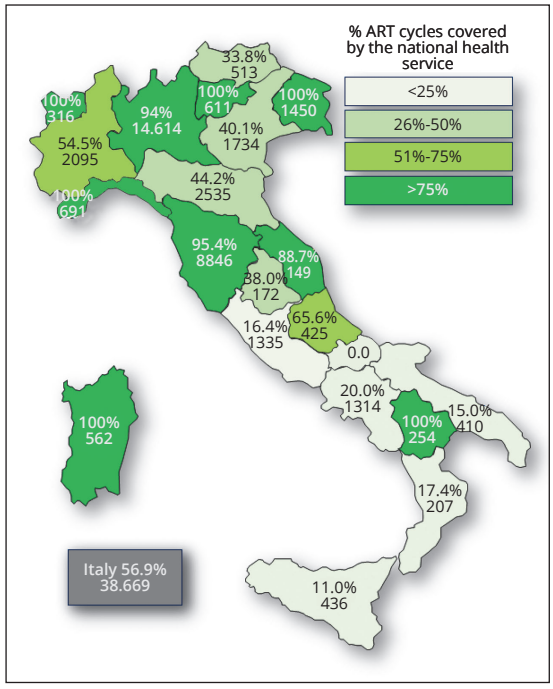

Figure 1.—Regional distribution of ART cycles covered by the national health services.

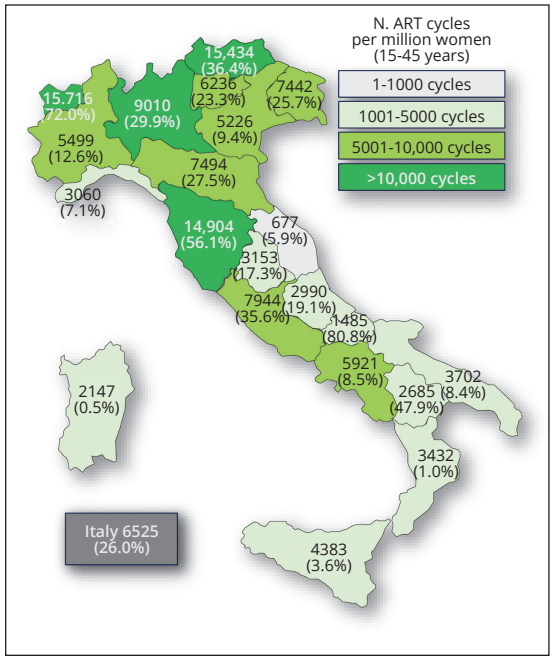

Figure 2.—Regional distribution of the number of initiated ART cycles per million women of reproductive age (15-45 years)* and in brackets the percentage of initiated cycles performed in patients coming from other regions, 2020.
*Average resident population in Italy in 2020 (data from ISTAT).

served that in some small regions, the percentage of public activity reaches 100% because there are only public centers, although they offer a limited number of ART cycles (Figure 1).

The EIM considers the number of ART cycles per million women of childbearing age (15-45 years) and/or per million inhabitants to be a reliable indicator to evaluate ART accessibility.[10, 11] The number of cycles performed per million women of childbearing age in Italy was 6.525, with large regional diversity. For instance, Tuscany and Lombardy had cycle rates per million women of childbearing age that were higher than the national average, at 14,904 and 9,010, respectively (Figure 2). This figure also includes the percentage of cycles that were carried out on patients who resided in other regions, so, the phenomenon of interregional migration can be observed. This could partially contribute to the availability of ART procedures. In Tuscany, 56.1% of cycles were performed on patients from other regions, while in Lombardy this percentage was 29.9%. In Lazio and Emilia Romagna, the number of cycles for million women of childbearing age is in line with the national average with 7944 and 7494 cycles, respectively. The percentage of cycles carried out on women from other regions vary: in Emilia Romagna, the figure was 27.5%, and in Lazio 35.6%.

The number of cycles per million women of childbearing age tended to be below the national average in many Italian regions, particularly in the central south. Of the regions with the most activity in this area, in Campania there were 5921 cycles per million women of childbearing age; in Sicily, there were 4383 cycles per million women of childbearing age; and in Puglia, there were 3702 cycles per million women of childbearing age.

There were 86 public or NHS-covered private centers that performed ART techniques, and 99 private centers (Supplementary Digital Material 2: Supplementary Table II). Of cycles performed using the couple's gametes, 61.2% were performed in NHS centers. In contrast, for cycles using gamete donation, 71.7% of cycles were performed in private centers (Supplementary Digital Material 3: Supplementary Table III).

There were 38 centers that performed at least 500 cycles and performed 56.5% of all ART cycles. Fewer than 200 cycles per year were performed at 44.8% of centers, which contributed only 12.3% of all ART cycles (Supplementary Digital Material 4: Supplementary Table IV).

From 2005 to 2019, ART cycles performed in Italy and the number of live births followed an upward trend. The number of initiated cycles increased by 121%, from 37,293 to 82,476.

The donation techniques have increased from 209 cycles in 2014 to 8995 in 2019 and 8787 in 2020. In the last year, a reduction in cycles performed with couples' gametes has been observed, while the number of techniques carried out with gamete donation remained constant (Figure 3A).

The percentage of infants born alive in the nation as a result of the use of ART techniques increased from 0.66 to a maximum of 3.05 per 100 live births in 2019 (Figure 3B).

Activity decreased in 2020 due to the SARS-CoV-2 pandemic, with a consequent reduction in the number of cycles performed and babies born.[9]

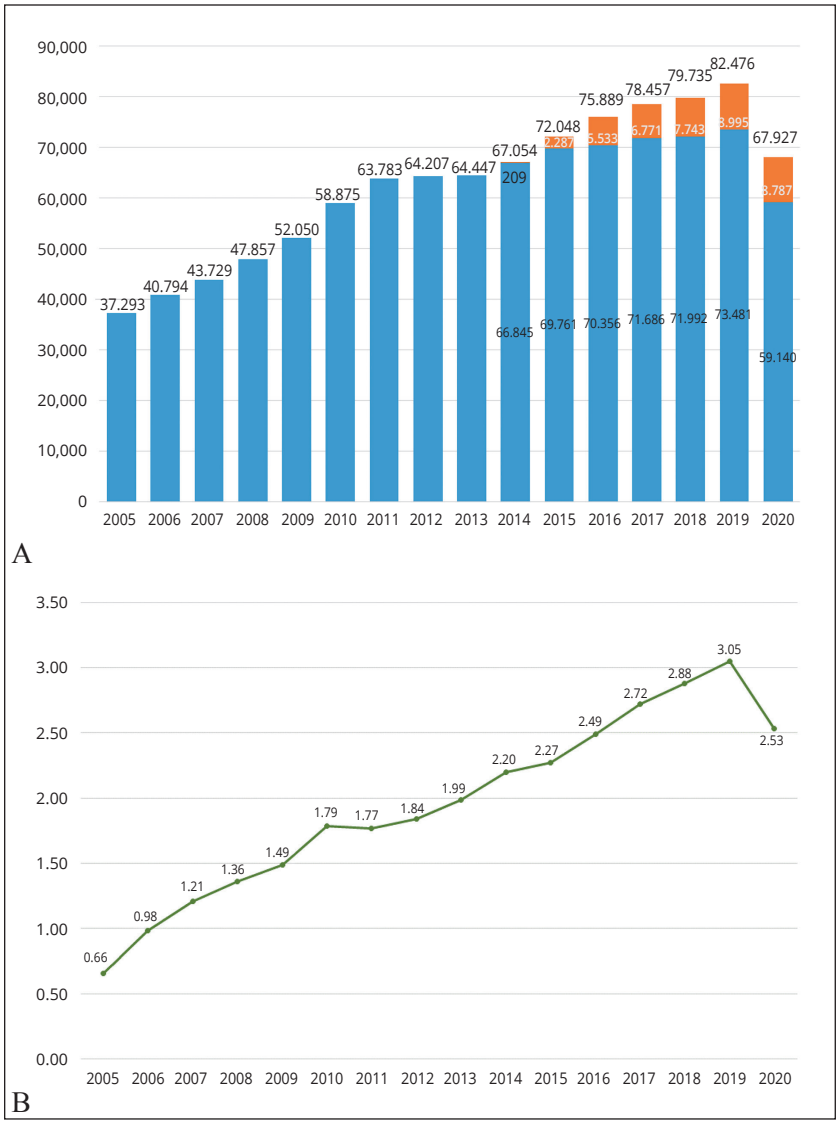

Figure 3.—Number of ART cycles (A) and percentage of ART babies born on general population births (%) (B), 2005-2020.

Pregnancies and deliveries

The couple's gametes were used in 59,140 cycles, 38,727 of which were carried out utilizing fresh techniques, 19,314 using the FER technique, and 1099 using the FO technique. A total of 38,972 transfers were performed.

In 2020, 8787 cycles were initiated involving gamete donation. Specifically, there were 7251 with OD (513 cycles with double gamete donation), and 1536 cycles with SD. Transfers performed with donated gametes numbered 7752.

Of all ART transfers, 64.8% was performed with one embryo, with a higher percentage in the FER cycles (79.4%) and in gamete donation (76.8% OD and 62.6% SD). Transfers with three or more embryos generally represented 3.4% of total transfers.

Pregnancy rates per transfer were 26.7% with fresh techniques, 32.6% with FER, and 25.7% with FO. For gamete donation, the pregnancy rate per transfer was 38% with OD and 39.1% in cycles with SD.

The delivery rate per number of embryo transfers was 17.1% for fresh technique, 22.5% for FER and 17.1% for FO. Live births using the couple's gametes numbered 8195. The delivery

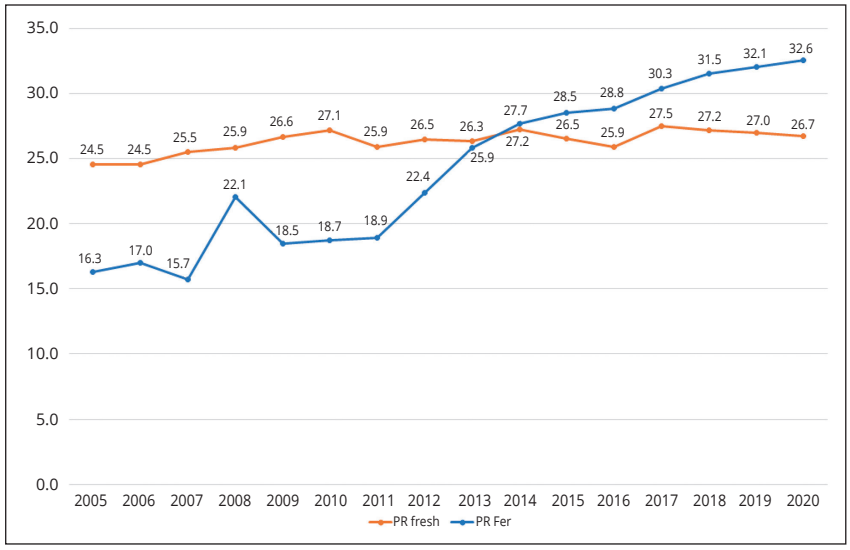

Figure 4.—Pregnancy rate per transfer, fresh *versus* FER cycles, 2005-2020.

rates per embryo transfer for techniques involving gamete donation were very similar for the different kinds of donated gamete: 25.1% for OD and 26.0% for SD. In total, 2063 children were born alive following the application of these techniques (Supplementary Digital Material 5: Supplementary Table V).

The FER technique is more effective in all age groups, with clear differences especially in patients older than 35 years (Supplementary Digital Material 6: Supplementary Table VI).

From 2014, the efficacy of FER cycles become higher than that of fresh cycles. In 2020, FER pregnancy rate was 32.6%, compared with 26.7% for fresh techniques (P<0.001) (Figure 4).

Safety of the techniques applied

From 2005 to the present, the application of both fresh and thawed ART techniques has shown a marked decrease in transfers with three or more embryos (from 48.6% to 3.9%) and a corresponding increase in single embryo transfers (from 19.1% to 62.8%). Consequently, in these sixteen years of activity, there has also been a decrease in twin deliveries (from 20.7% in 2005 to 7.0% in 2020) and in triplet deliveries (from 2.5% to 0.1%) (Figure 5A, B).

According to the patient's age, the frequency of transfers with three or more embryos increased with patient's age, from 1.9% in patients under 35, reaching 12.5% in those over 42. Nevertheless, multiple deliveries decreased from 8.2% in younger patients to 2.2% in older ones. In total, there were only five triplet births, 0.1% of all births (Table I).

Of the 14,462 pregnancies achieved by ART techniques, information about their outcomes is known for 90%. There is a loss of information at follow-up of 10% of pregnancies, which is higher for techniques using donated gametes.

Pregnancy loss occurs in 26.6% when ap-

TABLE I.—*Number of embryos transferred after ART with couples' gametes and multiple deliveries by women age groups in 2020.*

Age	<35 years	35-39 years	40-42 years	≥43 years	Overall
Transfers	12,890	15,343	7826	2913	38,972
One embryo (%)	67.5	63.6	56.9	53.7	62.8
Two embryos (%)	30.6	33.6	36.9	33.7	33.3
Three or more embryos (%)	1.9	2.8	6.2	12.6	3.9
Delivery	3372	3320	848	139	7679
Single (%)	91.8	93.1	95.9	97.8	92.9
Twin (%)	8.2	6.8	3.9	2.2	7.0
Triplet (%)	0.0	0.1	0.2	0.0	0.1

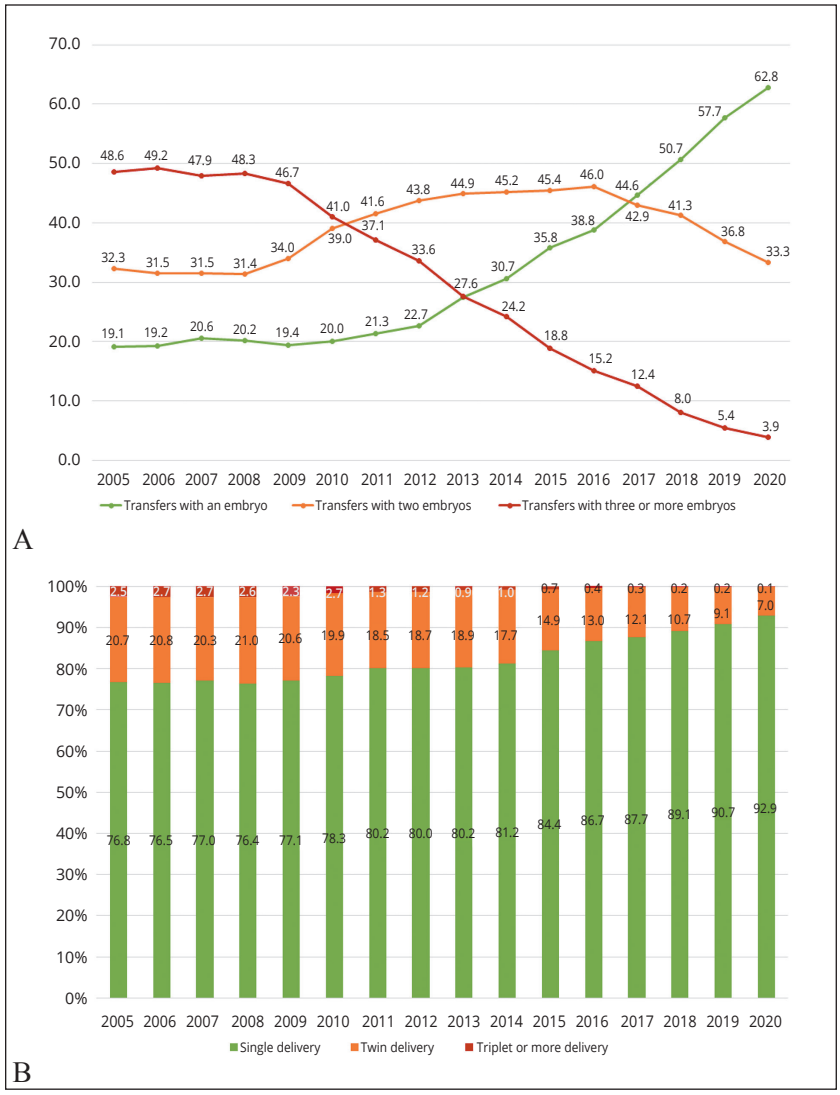

Figure 5.—Percentage of ART transfer by number of embryos transferred (A) and percentage of singleton, twin and triplet ART delivery (B), 2005-2020.

TABLE II.—*Outcome of clinical pregnancies after ART techniques in Italy in 2020.*

Parameters	Couples' gametes			Donor gametes		Overall
	Fresh cycles (IVF and ICSI)	FER	FO	OD	SD	
N. of clinical pregnancies	5197	6096	210	2513	446	14,462
Pregnancies lost to follow-up (%)	12.8	6.8	11.9	12.7	13.5	10.2
N. of monitored pregnancies	4534	5684	185	2195	386	12,984
Pregnancies loss (%) [a]	26.6	25.9	24.3	24.4	23.3	25.8
Live born babies	3660	4382	153	1743	320	10,258
Stillborn	17	16	1	13	1	48
Neonatal stillbirth [b]	13	9	0	9	2	33
Born with malformations	17	40	0	12	4	73

Fresh cycles: techniques with transfers without using cryopreserved gametes, includes IVF (*in-vitro* fertilization) and ICSI (intracytoplasmic sperm injection).
FER: frozen embryo replacement; FO: frozen/warm oocyte cycle; OD: oocyte donation (includes double donation); SD: semen donation.
[a] Pregnancies loss: pregnancy negatives exist (spontaneous abortions, therapeutic abortions, ectopic pregnancies); calculated on monitored pregnancies; [b] neonatal stillbirth: the death of a baby within the first 28 days of life.

plying fresh techniques, 25.9% with FER, and 24.3% with FO. The differences are not statistically significant for 2020 as during all the previous years (Table II).

Preimplantation genetic tests (PGT)

In Italy in 2020, 3598 ART cycles applying genetic investigations (PGT) were performed. These cycles were performed in 57 ART centers: 40 private, 10 NHS-covered private, and seven public. The majority of cycles with PGT were performed in private centers, and 83.5% in large centers with at least 500 ART cycles per year. The pregnancy rate per transfer in cycles with PGT was 44.5%, while the delivery rate was 35.2%. A total of 833 children were born alive after the application of these techniques (Supplementary Digital Material 7: Supplementary Table VII).

Intrauterine insemination (IUI)

IUI activity could be performed both in ART Centers and in IUI labs. In 2020, 11,679 IUI-H cycles were performed, with a pregnancy rate of 11.1%. The delivery rate was 7.7%, with 963 live births. Pregnancy loss occurred in 21.5% of cases. IUI-D cycles were 492 cycles, with a pregnancy rate of 22.2%. Pregnancy losses occurred in 21.7% and the delivery rate was 14.6%, with 84 live births (Supplementary Digital Material 8: Supplementary Table VIII).

Discussion

Italy is one of the European countries with the most intensive use of IVF techniques. In 2018, it was the 4th most active European country for MAR in the EIM Data Collection.[11] However, access to services is heterogeneous across regions. There is a distinct gap between the supply of services in the north and center regions of the country compared to in the southern regions, which can be measured in terms of cycles performed in a year. Moreover, access to services covered by the National Health System is profoundly unbalanced. Cycles performed in private centers represent 12.6% of cycles in the northeast, while in the southern regions they make up 77.4%.

Since the first data collection performed by the Italian MAR Register in 2005, there has been an increase in the application of MAR techniques, and the proportions of ART live birth increased from 0.66% in 2005 to 3.05% in 2019 of all live births in the country.

In 2020, there was a reduction in activity for the first time, mainly due to the restrictions brought on by the SARS-CoV-2 pandemic. This reduction in activity affected public centers the most, because unlike private centers they were unable to compensate for the loss of activity recorded in the first period of the year when centers were completely closed.[9]

The rate of cycles in which cryopreserved embryos (FER) are used continues to increase and in 2020 they reached 32.7%. If this figure is compared with the reduction of fresh cycles, we can perceive the change in strategies and treatment plans for patients. There is a tendency to postpone the transfer of embryos to the uterus from the time of stimulation and subsequent retrieval. This increase in the application rate of the FER technique is in line with what is happening in other European countries. In the latest available survey year of the EIM, which refers to 2018, it is observed that the application of the FER technique made up 33.4% of all the techniques performed. Referring only to the countries with the longest tradition in the field of IVF, this ranged from 39.2% in France to 27.9% in Germany.[11]

For the first time in fresh techniques, single embryo transfers performed exceeded two embryo transfers. This brings Italy in line with clinical performance in the rest of Europe, where in 2018 overall, the number of single embryo transfers using fresh techniques was 50.7%. This aligns Italy with countries such as France but still far from the UK, where 64.5% of transfers are performed with a single embryo, or from northern European countries like Denmark or Sweden, where fresh techniques make up 80.6% and 87.3% of single embryo transfers, respectively.[11]

The number of cycles in which preimplantation genetic investigations were performed has increased, as has those performed with gamete donation. The number of twin and triplet deliveries have decreased in all the techniques applied.

Conclusions

Since the date of its establishment in 2005, the ItMARR has been providing information regarding MAR to give a comprehensive picture of the activity of all Italian centers. This information on the availability and utilization of the techniques, their results, and the safety of their application, is becoming a great asset in the reproductive health scenario. The standardization of national data collection on the application of MAR has allowed better information dissemination and improvement of the standard quality of techniques.

Information is spread by the Register through its own website (www.iss.it/rpma) and at different levels. The Minister of Health makes an annual presentation to the Italian Parliament to fulfill law 40/2004 and the regional authorities can monitor the activity in their territory. The network of MAR centers, different scientific societies and patients' associations, and the citizens can also access the data.

Moreover, the Registry establishes some key performance indicators (KPI) give to each center the opportunity to evaluate their own activity and therefore to improve it.

The ItMARR has been working to perform a cycle-by-cycle data collection in the near future that will bring the Italian data collection system in line with other European countries that are already at the forefront of reporting MAR activity. The new data collection system will guarantee more transparency in data dissemination.

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Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions
Giulia Scaravelli: conception and design, data interpretation, critical revision of the manuscript. Roberto De Luca: data interpretation, critical revision of the manuscript, data analysis. Roberta Spoletini,Lucia Speziale, Fabiola Fedele, Simone Bolli, Monica Mazzola, Anna Bertini, and Cinzia Di Monte: data interpretation, critical revision of the manuscript. Vincenzo Vigiliano: conception and design, data analysis, data interpretation, drafting the manuscript, critical revision of the manuscript. All authors read and approved the final version of the manuscript.

History
Article first published online: February 29, 2024. - Manuscript accepted: December 15, 2023. - Manuscript revised: November 16, 2023. - Manuscript received: June 22, 2023.

Supplementary data
For supplementary materials, please see the HTML version of this article at www.minervamedica.it