

P R A C E O R Y G I N A L N E
niepłodność

Assisted reproductive medicine in Poland – Fertility and Sterility Special Interest Group of the Polish Gynaecological Society (SPiN PTG) 2012 report

Medycyna wspomaganego rozrodu w Polsce – raport za rok 2012 Sekcji Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego (SPiN PTG)

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Abstract

Objectives: The aim of this report is to present data concerning results and complications related to infertility treatment using assisted reproductive technology (ART) and insemination (IUI) in Poland in 2012.

Material and methods: The report was prepared by the Fertility and Sterility Special Interest Group of the Polish Gynaecological Society (SPiN PTG), based on individual data provided by fertility clinics. Reporting was voluntary, data were not subject to external verification. The report presents the availability and the structure of infertility treatment services, the number of procedures performed, their effectiveness and the most common complications.

Results: In 2014, 34 Polish fertility clinics provided information to the report, presenting data from 2012. The total number of reported treatment cycles using ART was 17,116 (incl. 10,714 fresh IVF/ICSI) and 14,727 IUI. The clinical pregnancy rate per cycle was on average 33.7% for fresh IVF/ICSI and 13.3% for IUI. The prevalence of multiple births was 15.7% and 6.2%, in case of IVF/ICSI and IUI methods respectively. The most frequent complication in the course of treatment using ART was ovarian hyperstimulation syndrome (OHSS) - severe OHSS constituted 0.68% of all stimulated cycles.

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Conclusions: The SPiN PTG report shows the average effectiveness and safety of ART and was the only proof of responsibility and due diligence of fertility centres in Poland. However, due to the lack of a central register of fertility clinics, facultative participation in the report as well as incomplete information on pregnancy and delivery rate, the collected data do not reflect the full spectrum of Polish reproductive medicine.

Key words: **infertility treatment / assisted reproductive technology / IVF/ICSI / insemination / IUI / fertility /**

Streszczenie

Cel pracy: Celem publikacji jest przedstawienie danych dotyczących rezultatów i powikłań związanych z leczeniem niepłodności z wykorzystaniem wysokospecjalistycznych technik wspomaganego rozrodu (ART) i inseminacji (IUI) w Polsce w 2012 roku.

Materiał i metody: Raport został opracowany przez Sekcję Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego (SPiN PTG) w oparciu o dane indywidualne udostępnione przez kliniki leczenia niepłodności zlokalizowane na terenie Polski. Raportowanie miało charakter dobrowolny, a przesłane dane nie podlegały kontroli zewnętrznej. W raporcie przedstawiono dostępność i strukturę usług z zakresu leczenia niepłodności, liczbę przeprowadzonych procedur, ich skuteczność oraz najczęstsze komplikacje.

Wyniki: W 2014 roku, przedstawiając dane za 2012 rok, do raportu SPiN PTG przystąpiły 34 polskie kliniki leczenia niepłodności. Odnotowano łącznie 17116 cykli leczenia z zastosowaniem ART (w tym 10714 procedur IVF/ICSI) i 14727 zabiegów IUI. Odsetek ciąż klinicznych w przeliczeniu na cykl wyniósł 33,7% w przypadku procedur IVF/ICSI i 13,3% w przypadku IUI. Porody wielopłodowe występowały z częstością 15,7% i 6,2% odpowiednio w przypadku metod IVF/ICSI i IUI. Do najczęstszych komplikacji w przebiegu leczenia z zastosowaniem ART należał zespół hiperstymulacji jajników (OHSS) – ciężki OHSS stanowił 0,68% wszystkich cykli stymulowanych.

Wnioski: Raport SPiN PTG pozwala na poznanie średniej skuteczności i bezpieczeństwa technik wspomaganego rozrodu i jest obecnie jedynym dowodem odpowiedzialności i rzetelności medycznej ośrodków zajmujących się leczeniem niepłodności w Polsce. Jednakże ze względu na brak centralnego rejestru klinik leczenia niepłodności, fakultatywny charakter udziału w raporcie oraz braki w monitoringu przebiegu ciąży i porodów zebrane dane nie stanowią pełnego obrazu polskiej medycyny rozrodu.

Słowa kluczowe: **leczenie niepłodności / techniki wspomaganego rozrodu / IVF/ICSI / inseminacja / IUI / raport Sekcji Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego /**

Introduction

Infertility is a disease defined by the World Health Organisation (WHO) as failure to achieve pregnancy after 12 months of regular unprotected sexual intercourse. Currently ca. 1.2 million couples in Poland suffer from infertility and subfertility. Minimum 2%, i.e. 24,000 couples a year require ART (assisted reproductive technology) treatment with the use of *in vitro* fertilisation. Due to growing needs and expectations of the society as well as the necessity to introduce family-friendly actions to prevent the demographic decline, it is predicted that importance of infertility treatment and ART will increase in the next few years.

For many years the safety and effectiveness of methods applied in infertility treatment have been assessed. National reports presenting data on ART and intrauterine insemination (IUI) are extremely valuable source of information in this field.

The unit responsible for collecting, processing and publication of these data in Poland is the Fertility and Sterility Special Interest Group of the Polish Gynaecological Society (Sekcja Płodności i Niepłodności Polskiego Towarzystwa Ginekologicznego, SPiN PTG).

Since 2001 SPiN PTG has prepared reports on availability, safety and effectiveness of infertility treatment using ART and IUI. Collected data are published on the website of the Group (www.spin.org.pl) and shared with the European Society of Human Reproduction and Embryology (ESHRE) within the European IVF Monitoring (EIM) program. The first report depicting the situation in Poland in 2011 was published in 2014 [1].

The data obtained from all European countries participating in EIM have been published annually since 1997 in Human Reproduction (last publication from July 2014 contains data from the year 2010 [2]).

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Aim

The aim of this publication is to present data regarding the use of ART in Poland in 2012 as well as the number of procedures performed, the availability, and structure of the offered services. Moreover, collected data allow to present the average effectiveness of the treatment and to learn about the most frequent treatment-related complications. It is the base for comparison with treatment results achieved in other countries.

Material and methods

Information about the report for the year 2012 was sent per e-mail to 41 centres in Poland dealing with infertility treatment using *in vitro* methods and (or) insemination. Mailing data and the information about the activity profile were found through scientific and professional societies, personal communication and clinics' websites. Due to lack of national central register of infertility clinics and wishing to reach all interested units, the report form was also published on-line on SPiN PTG website.

Reporting was voluntary. Clinics were not obliged to participate in the project and the provided data were not subject to any control or external verification. Reports were only checked for completeness and data convergence between tables. Using individual data sent by infertility clinics, a joint report was prepared. Individual data of particular centres remain confidential.

Final report incorporates infertility treatment procedures which started between 1st of January and 31st of December 2012 and includes the following data:

1. The number of clinics participating in the report, including the number of ART and IUI procedures performed.
2. The number and effectiveness of the ART procedures, including:
 - a. IVF (*in vitro* fertilisation) and ICSI (intracytoplasmic sperm injection);
 - b. FER (frozen embryo replacement);
 - c. PGD (preimplantation genetic diagnosis);
 - d. IVM (*in vitro* maturation);
 - e. FOR (frozen oocyte replacement);
 - f. ED (egg donation);
 - g. Transfer of embryos donated from another couple (embryo donation).

The data for IVF, ICSI, FER and ED also include the division according to the age of patients, number of embryos replaced, number of clinical pregnancies, number of deliveries and their result (single/multiple birth, date of delivery)

3. Perinatal risks and complications recorded during the ART procedure.
4. Number and result of the IUI-H (intrauterine insemination using husband's/partner's semen) or IUI-D (IUI-D, intrauterine insemination using donor semen).
5. Cross-border reproductive care (CBRC).

The terminology is applied in accordance with that proposed by ESHRE, the International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) [1, 3].

Results

Feedback was obtained from 34 centres out of 41 questioned (4 public and 30 private). Thirty clinics shared data regarding ART methods and IUI, 3 clinics provided data for *in vitro*

techniques only and 1 clinic for insemination. A list of all centres participating in the report is presented in Table I.

1. Size of the clinics

Out of the 33 centres reporting on ART use, 14 centres (42.4%) are small clinics, performing fewer than 200 treatment cycles a year, 12 centres (36.4%) are medium-size clinics, performing 200-499 cycles a year, 7 clinics (21.2%) are centres with a large number of cycles performed (over 500 a year), including one clinic performing over 1,000 procedures a year. The total annual number of initiated cycles for IVF, ICSI, FER, PGD, ED, IVM, FOR was taken into account.

2. Number of treatment cycles

In 2012 a total number of 17,116 treatment cycles using ART was recorded, including embryo donation. Fresh IVF/ICSI procedures constituted 10,714 cycles (703 more than in 2011), 461 (4.3%) of them consisted of IVF only and 10,253 of them were ICSI or mixed IVF and ICSI (95.7%) procedures. In 428 cases (4.0%) donor semen was used and 163 cycles (1.5%) were performed with surgically obtained husband's/partner's semen.

FER cycles were performed 4,969 times (439 more in comparison with the year 2011). The incidence of FER was high, constituting 46.4% of the fresh IVF/ICSI cycles.

Moreover 244 PGD, 713 ED, 70 IVM, 139 FOR cycles and 267 procedures with embryo donation were reported (in 2011: 190, 661, 33, 79 and 251 respectively).

3. Treatment effectiveness

Infertility treatment with ART initiated in 2012 resulted in 5,445 clinical pregnancies (clinical pregnancy diagnosed with clinical and ultrasonographic parameters in accordance with the WHO/ICMART definition: gestational sac visible on ultrasound; including ectopic pregnancy).

Four thousand ninety five registered deliveries resulted in birth of 4,694 children: 3,182 (67.8%) following IVF/ICSI, 1,030 (21.9%) following FER, 290 (6.2%) following ED, 58 (1.2%) following PGD, 61 (1.3%) following IVM or FOR and 73 (1.6%) following embryo donation. In case of deliveries with unknown result, single deliveries were assumed for calculations (146 deliveries following ART). The course of 627 clinical pregnancies (11.5% of all pregnancies) is unknown.

3.1. IVF, ICSI and FER procedures

Pregnancy rate per aspiration for IVF and ICSI amounted to 29.3% (135/461) and 33.9% (3471/10253) respectively, and in case of FER was 26.5% (1317/4969). Pregnancy rates per transfer were: 34.4% (135/392), 39.8% (3471/8714), and 27.8% (1317/4736) respectively.

Delivery rate is impossible to calculate due to significant losses in the follow-up of pregnancies, amounting respectively to 23.0% (31/135), 11.8% (411/3471), 12.8% (169/1317) for IVF, ICSI and FER. According to the reported data 10 miscarriages were noted after IVF (7.4%), 414 after ICSI (11.9%) and 220 after FER (16.7%). However, it cannot be precluded that the percent of pregnancy losses is higher. Lack of thorough assessment is caused by incomplete monitoring.

3.2. Egg and embryo donation

Infertility treatment with egg donation was reported by 17 clinics.

Table I. A list of centres participating in the SPiN PTG report in 2012.

| | | | | | |
|-----|---|---|-----|--|---|
| 1. | AB OVO Sp. z o.o. NZOZ Centrum Zdrowia Rodziny | ul. Bociania 6, 20-542 Lublin | 19. | Klinika Niepłodności i Endokrynologii Rozrodu Uniwersytet Medyczny w Poznaniu | ul. Polna 33, 60-535 Poznań |
| 2. | ANGELIUS Szpital PROVITA | ul. Fabryczna 13d, 40-611 Katowice | 20. | Klinika Rozrodczości i Endokrynologii Ginekologicznej Uniwersytecki Szpital Kliniczny w Białymstoku wraz z ARTEMIDA Domitry i Partnerzy – Centrum Ginekologii, Endokrynologii i Medycyny Rozrodu | ul. Marii Skłodowskiej-Curie 24a, 15-276 Białystok ul. Włókniennicza 9B/U, 15-464 Białystok |
| 3. | ANTRUM NZOZ Centrum Medyczne, Laboratorium DEMETER Stanisław Horák | ul. Olimpijska 5, 41-902 Bytom | 21. | KRIOBANK Centrum Leczenia Niepłodności Matżeńskiej | ul. Stoleczna 11, 15-879 Białystok |
| 4. | ARTVIMED Centrum Medycyny Rozrodu | ul. Legendy 3/1, 30-147 Kraków | 22. | MACIERZYŃSTWO Centrum Medyczne | ul. Białoprądnicka 7A, 31-221 Kraków |
| 5. | BOCIAN Klinika Leczenia Niepłodności, Ginekologii i Płodnictwa | ul. Akademicka 26, 15-267 Białystok | 23. | MedART Sp. z o.o. Ośrodek Diagnostyki i Leczenia Niepłodności | ul. Słowiańska 55c, 61-664 Poznań |
| 6. | GAMETA Szpital Rzgów - Klinika Leczenia Niepłodności | ul. Rudzka 34/36, 95-030 Rzgów | 24. | NOVOMEDICA Sp. z o.o. Centrum Leczenia Niepłodności | ul. Ks. N. Bończyka 34, 41-400 Mysłowice |
| 7. | GAMETA Centrum Zdrowia | ul. Kościuszki 11, 25-310 Kielce | 25. | nOvum Przychodnia Lekarska | ul. Bociania 13, 02-807 Warszawa |
| 8. | GAMETA Centrum Zdrowia | ul. Derdowskiego 7, 81-369 Gdynia | 26. | Ośrodek Diagnostyki i Leczenia Niepłodności I Katedra i Klinika Płodnictwa i Ginekologii UM w Warszawie | pl. Starynkiewicza 1/3, 02-015 Warszawa |
| 9. | GENESIS Klinika Leczenia Niepłodności NZOZ Centrum Medyczne | ul. Waleńowa 24, 85-435 Bydgoszcz | 27. | OVUM Rozrodczość i Andrologia Sp. z o. o. | ul. Staszica 14, 20-081 Lublin |
| 10. | GMW EMBRIO Sp. z o.o. | ul. Obrońców Stalingradu 61, 45-594 Opole | 28. | PARENS Centrum Leczenia Niepłodności | al. 29 Listopada 155c, 31-406 Kraków |
| 11. | GRAVIDA S.C. Specjalistyczny Ośrodek Ginekologii, Płodnictwa i Leczenia Niepłodności | ul. Armii Krajowej 21, 09-410 Płock | 29. | PARENS Rzeszów Sp. z o.o. | ul. Podwłocze 21, 35-309 Rzeszów |
| 12. | GRAVITA Diagnostyka i Leczenie Niepłodności | ul. gen. Karola Kniaziewicza 20a, 91-347 Łódź | 30. | POLAK NZOZ sc | ul. Partynicka 45, 53-031 Wrocław |
| 13. | GYNCENTRUM CLINIC Sp. z o.o. Klinika Leczenia Niepłodności i Diagnostyki Prenatalnej | ul. Żelazna 1, 40-851 Katowice | 31. | SALVE-MEDICA Klinika Leczenia Niepłodności | ul. Szparagowa 10, 91-211 Łódź |
| 14. | INVICTA Klinika Leczenia Niepłodności | ul. Rajska 10, 80-850 Gdańsk | 32. | VitroLive Sp. z o.o. Centrum Ginekologii i Leczenia Niepłodności VitroLive | ul. Kasprzaka 2A, 71-074 Szczecin |
| 15. | INVICTA Klinika Leczenia Niepłodności | ul. Złota 6, 00-019 Warszawa | 33. | ZDRÓWKO Klinika s.c. Iwona Adamczak, Rafał Adamczak | ul. Aleja Adama Mickiewicza 23, 86-032 Niemcz |
| 16. | INVIMED Europejskie Centrum Macierzyństwa | ul. Rakowiecka 36, 02-532 Warszawa | 34. | Zięba Clinic | ul. Kościuszki 255A, 40-608 Katowice |
| 17. | INVIMED Europejskie Centrum Macierzyństwa | ul. Dąbrowskiego 44, 50-457 Wrocław | | | |
| 18. | Laboratorium Wspomaganego Rozrodu SPSK1 im. Tadeusza Sokołowskiego w Szczecinie | ul. Siedlecka 2, 72-010 Police | | | |

In 2012 the following number of procedures was performed:

- 312 (13 less than in 2011) treatment cycles with the donation of fresh (n=268) or frozen (n=44) egg cells;
- 713 (52 more than in the year 2011) procedures of embryo transfer following fertilisation of a donated egg cell, including: 420 embryo transfer procedures following fresh ICSI-ED, 65 after FOR-ED and 228 following FER-ED.

Pregnancy rate per embryo transfer was equal to: 47.4% (199/420) for fresh ICSI-ED, 38.5% (25/65) for FOR-ED and 33.8% (77/228) for FER-ED. Two hundred forty one deliveries and 44 miscarriages were reported, the course of 5.3% clinical pregnancies (16/301) remains unknown. Two hundred ninety children were born as a result of egg donation.

Ten centres reported the embryo donation procedures (n=267). As a result, 35.6% (95/267) infertile couples conceived and 27.3% (73/267) had a baby.

3.3. Preimplantation genetic diagnosis (PGD)

Preimplantation genetic diagnosis was reported by 3 centres. There were 244 treatment cycles performed using fresh and FER PGD (54 more than in 2011). One hundred thirty six of them ended up with embryo transfer – 57 patients got pregnant (41.9%), there were 5 miscarriages (3.7%) and 52 deliveries (38.2%).

3.4. In vitro maturation (IVM)

The data regarding the effectiveness of treatment using the IVM method were sent by 4 clinics. In total, 70 aspirations (37 more than in 2011) and 48 embryo transfers were reported, which resulted in 20 clinical pregnancies and 18 deliveries (pregnancy and delivery rate per aspiration amounted to 28.6% and 25.7% respectively).

3.5. Frozen oocyte replacement (FOR)

The use of frozen egg cells for fertilisation was reported by 12 clinics. In total 139 FOR cycles were performed (60 more than in 2011), including 126 cycles concluded with embryo transfer. In 49 cases clinical pregnancy was diagnosed (35.3%) and 43 patients had a baby (30.9%).

4. The age of the patients

The largest group of patients treated with IVF, ICSI and FER were women before 35 years of age (60.0%, 54.7%, 54.4% respectively). This group was also characterised by the highest effectiveness of treatment. The percentages of clinical pregnancies per aspiration amounted to: 33.3% in case of IVF, 39.6% in case of ICSI and 29.0% in case of FER. The group of patients over 40 years of age was the smallest (12.2%, 12.4% and 9.4% respectively for the IVF, ICSI and FER methods) and the treatment was least effective (21.8%, 17.0% and 15.8% clinical pregnancies respectively counted per aspiration) (Table II).

On the contrary, procedures with donated egg cells were rather performed in older patients, over 40 years of age (41.5%), rarely in women before 35 years of age (22.8%). The pregnancy rate per embryo transfer in particular age groups was as follows: women aged ≤34 years: 39.9% (65/163), patients aged 35-39: 48.8% (124/254) and ≥40 years: 37.8% (112/296).

5. The number of transferred embryos vs. multiple births

In case of fresh IVF/ICSI cycles the predominant policy, as in 2011, was to transfer maximum of 2 embryos (93.9%).

Single embryo transfer (SET) constituted 24.7% of all procedures, including 54.1% for elective single embryo transfer (eSET). Double embryo transfer (DET) represented 69.2%, transfer of three embryos – 6.0% and transfer of four or more embryos happened only sporadically and constituted only 0.07% of all transfers.

In case of FER cycles the proportion of transfers of 1, 2, 3 and ≥4 embryos was: 28.4%, 61.7%, 7.4% and 0.2%, respectively (in case of 2.3% transfers the number of transferred embryos remains unknown). In case of ED procedures the proportion was: 22.7%, 70.4%, 6.6% and 0.3% respectively.

The percent of multiple births following infertility treatment using IVF/ICSI was equal to 15.2% for twins and 0.5% for triplets. In case of FER: 10.8% and 0.1% and for ED 18.7% and 0.8%, respectively. Table III presents detailed relationship between the number of transferred embryos and number of children born after fresh IVF/ICSI.

6. Perinatal risks and other complications

The data regarding the incidence of preterm deliveries according to the number of newborns were shared by 11 clinics and it concerns the course of 945 deliveries after fresh IVF/ICSI, 454 after FER and 156 after ED. According to these data the incidence of preterm birth (gestational weeks 20-36) amounted to 27.3% for a singleton delivery, 55.5% for twins and 100% for triplets or higher order pregnancy, including extreme preterm birth (20-27 weeks): 1.9%, 6.8% and 0.0% respectively. Term delivery (37-41 weeks) rates were reported in 68.8% for singleton, 41.4% for twins and 0.0% for triplets.

The most common complication in the course of treatment was the ovarian hyperstimulation syndrome (OHSS). In 2012, 75 severe OHSS cases were reported, which constitutes 0.68% of all stimulated cycles. The most common complication at the stage of egg retrieval procedure was bleeding (n=43, 0.39%) and infections (n=7, 0.06%).

Table II. The rate of clinical pregnancies per oocyte retrieval in relation to the patient's age.

| ART | Woman's age | | |
|-------|----------------------|----------------------|---------------------|
| | ≤34 | 35-39 | ≥40 |
| IVF | 33.3% (90/270) | 26.4% (33/125) | 21.8% (12/55) |
| ICSI* | 39.6% (2168/5478) | 33.1% (1092/3298) | 17.0% (211/1241) |
| FER | 29.0% (783/2702) | 25.6% (460/1799) | 15.8% (74/468) |

* ICSI lub cykle mieszane IVF i ICSI; ICSI or mixed IVF and ICSI

7. Intrauterine insemination (IUI)

Data regarding the number, type and effectiveness of IUI were shared by 31 clinics. According to the report, in 2012 the centres performed a total number of 14,727 insemination procedures (900 less than in 2011), including 12,719 IUI-H and 2,008 IUI-D procedures. The majority of these procedures was performed in women before 40 years of age (91.9%).

Pregnancy rate per cycle was 13.3% (13.6% for women aged <40 years and 10.9% for women aged ≥40 years). Delivery rate was 8.7%, including 7.9% for IUI-H and 14.1% for IUI-D. The incidence of single deliveries was 93.8% (1100/1173), twins - 6.1% (72/1173) and triplets - 0.1% (1/1173) (only deliveries with a known result were taken into account for calculations).

8. Cross-border reproductive care (CBRC)

The data regarding the CBRC are based upon reports sent by 6 clinics.

The most numerous group of cross-border patients are the citizens of Germany (74.2%), followed by the citizens of the United Kingdom (6.2%), Austria (2.6%), Ireland (2.1%) and France (2.1%). The main reasons why foreigners decided to start treatment in Poland were: the differences in the availability of procedures resulting from the legal regulations in these countries (44.3%), reduced availability, including higher costs of treatment in home country, distance, the waiting time for procedures (3.1%) and previous failures (1.5%).

In total, 237 ART and 197 IUI procedures were recorded (1.4% and 1.3% of all reported - in 2012 treatment cycles using *in vitro* and IUI methods, respectively). The majority of foreign patients were treated by IUI-D (45.4% reported cycles). This was followed by ART methods: 21.0% couples underwent ICSI treatment using their own gametes, and there were 24.2% procedures with donor egg cells and 9.4% with donor semen.

Discussion

The following report is the 14th report of SPiN PTG on effectiveness, safety and availability of the assisted reproductive technology in Poland, the second one which was published in a Polish scientific journal [1]. The data covering years 2008-2012 were published via website of the Group (spin.org.pl) and the data covering years 1999 – 2010 were published in Human Reproduction as a part of EIM Program [2, 4 - 14].

Table III. The rate of single and multiple births according to the number of transferred embryos following IVF/ICSI.

| Number of transferred embryos | Deliveries with known outcome (n) | Single deliveries (%) | Twins (%) | Triplets + (%) |
|-------------------------------|-----------------------------------|-----------------------|-----------|----------------|
| 1 | 555 | 99,1 | 0,9 | 0 |
| *eSET | 368 | 98,9 | 1,1 | 0 |
| 2 | 2060 | 80,6 | 19,0 | 0,3 |
| 3 | 119 | 79,0 | 16,0 | 5,0 |
| ≥4 | 0 | 0 | 0 | 0 |
| Total | 2734 | 84,3 | 15,2 | 0,5 |

In 2014 (data for the year 2012) the report was joined by 33 Polish *in vitro* clinics, evaluating 17,116 ART cycles. That database constitutes a valuable and unique source of information about the status of reproductive medicine in Poland. However, due to the lack of a central register of fertility clinics and facultative participation in the report, the following report cannot be considered as the whole reflection of that status. Full spectrum of reproductive medicine in Poland requires 100% attendance and unified standards consistent with recommendations of SPiN PTG and PTMR (Polish Society of Reproductive Medicine – Polskie Towarzystwo Medycyny Rozrodu) [15, 16]. Moreover, the data collected in a given calendar year relate to the period of last 2 years (due to the verification process of pregnancies and births). This is the objective reason that prevents „new” units from reporting.

The place of Polish reproductive medicine in comparison to other European countries is presented in ESHRE reports. According to the most recent report, covering year 2010, Poland is one of the 12 countries with the highest number of ART procedures performed ($n = 13.325$). Most of them are carried out in France, Germany, Italy, Spain and the UK (over 50,000 cycles per country per year). However, when we take into consideration the number of inhabitants, Poland is at the end of the list. In 2010, the number of ART cycles was 351 per million inhabitants and 1,630 per million reproductive age women¹, compared with the European average of 1.221 and 6.258² [2, 17]. According to the current report, in 2012 that figure increased in Poland to 437 and 2,103 cycles, respectively³ [18]. In fact, this percentage may be slightly higher, since not all ART clinics participated in the report. However, it does not change the fact that the use of ART methods in Poland is several times lower in comparison to other European countries. The highest use of assisted reproductive techniques is observed in Denmark, Belgium, and Iceland (over 2,500 cycles per million inhabitants treated and more than 12,000 per million women of reproductive age) [2].

The real need for assisted reproductive technology in Poland appears to be at least twice higher than the number of procedures performed. According to the forecasts of SPiN PTG and PTMR, approximately 20,000 – 24,000 couples each year require *in vitro* procedure. The following years will reveal the real range of this problem due to introduction of a Governmental Program “Leczenie Niepłodności Metodą Zapłodnienia Pozaustrojowego na lata 2013 – 2016”, which allows reimbursement of three *in vitro* fertilisation procedures. The Program was implemented on

July 1st, 2013. It has increased the number of patients treated, by including couples, for whom ART treatment was inaccessible due to financial reasons. The increase in the number of IVF/ICSI procedures in Poland is a positive sign, corresponding to the real needs and meeting the demographic trends. Currently, Poland is the country with one of the lowest fertility rates (total fertility rate, TFR = 1.3⁴). The low number of births is largely the result of fertility problems, while the percentage of children born through ART in Poland is only 1.2%. Corresponding data for Europe amount to nearly 2.5% (the highest percentage is Denmark – 5.9% and Slovenia - 5.1%) [2].

According to the report, infertility treatment in Poland compared to European average can be characterized by high effectiveness: 29.3% vs. 29.2% for IVF, 33.9% vs. 28.8% for ICSI and 26.5% vs. 20.3% for FER [2]. In comparison to the previous year, clinical pregnancy rate per fresh IVF/ICSI cycle in Poland in 2012 was 0.5 percentage points lower than last year (33.7% vs. 34.2%) [1].

A recent EIM report ranks Poland on the 7th place in terms of effectiveness of treatment using ICSI (out of 30 reporting countries). Higher pregnancy rate was recorded only in Romania (48.9%), Macedonia (41.3%), Moldova (39.6%), Ukraine (36.5%), Serbia (35.4%) and Austria (34.9%), i.e. the countries (except Austria), where reporting is optional or where there is a policy of transfer of ≥ 3 embryos (more than 50% of transfers were carried out using at least 3 embryos) [2]. In 2012 in Poland, same as in the previous year, in most cases no more than 2 embryos were transferred (93.9% transfers after IVF/ICSI).

1 The number of Polish residents in 2010 was 38,200 in thous., women of reproductive age: 15-44 years old were 8 236,6 in thous. [17]. The results of IVF, ICSI, FER, ED, IVM FOR and PGD were taken into consideration.

2 Data based on the analysis of the results for 16 countries where all clinics participated in the report and sent full details (Austria, Belgium, Czech Republic, Montenegro, Denmark, Finland, the Netherlands, Iceland, Macedonia, Norway, Portugal, Slovenia, Sweden, the UK, Italy).

3 The number of Polish residents in 2012 was 38,533 in thous., women of reproductive age: 16-44 years old were 8 012,4 in thous. [18]. The results of IVF, ICSI, FER, ED, IVM FOR and PGD were taken into consideration.

4 Total Fertility Rate that ensures simple replacement of generations is 2.1-2.15. Data for Poland by Eurostat: <http://ec.europa.eu/eurostat/help/new-eurostat-website>.

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A similar transfer policy can be observed in Austria, Denmark, Finland, Iceland, Ireland, Portugal, Slovenia, Sweden and the UK with an average pregnancy rate per transfer – 30.5% (the average in Europe, regardless of the number of transferred embryos – 28.9%) [2].

The weakness of the results presented for Poland is a declarative nature of the data reported and incomplete follow-up of pregnancies and deliveries (12.3% clinical pregnancies after IVF/ICSI). In 2012 there was no system to verify those data in Poland. Reporting remains a matter of diligence of the clinics which run their own databases and carry out statistical analysis.

Further data analysis shows, not surprisingly, a correlation between the number of transferred embryos and multiple births and timing of delivery. For the safety of mother and child, it is recommended to transfer a single embryo, that according to the report, is associated with the lowest risk of multiple pregnancy. In case of SET after IVF/ICSI, the percentage of multiple births was 0.9%, while for DET it increased to 19.4%, and in case of transfer of ≥ 3 embryos it was 21.0%. Each multiple pregnancy is associated with a higher risk of complications for mother and (or) her children. According to the present report, more than half of twins and all triplets were born prematurely. For 6.7% of multiple pregnancies the gestational age did not exceed the 27th week of pregnancy (vs. 1.9% for singletons).

Multiple pregnancies are the most important issue of infertility treatment using assisted reproductive techniques. The solution is eSET and freezing of remaining embryos for the future use. According to the recent studies such procedure does not have a negative influence on the effectiveness of the treatment. The cumulative percentage of pregnancies which are the result of eSET and FER is comparable to the results achieved with DET [19, 20]. The number of SET performed in Europe grows continuously (from 11.5% in 1997 to 25.7% in 2010). The highest percentage is recorded in Sweden (73.3%), Finland (67.5%), and Belgium (50.4%) [2]. SET constitute 24.7% of transfers in Poland - among that more than a half are eSET.

Infertility treatment has rarely been associated with serious adverse events. The most commonly observed adverse event in case of ovarian stimulation was OHSS (0.68% initiated treated cycles), and during the oocyte retrieval: bleeding (0.39%) and infections (0.06%).

The egg and embryo donation is for many people the only chance for having a baby. There has been a steady increase in the number of such procedures performed in Poland (number of transfers with ED in 2010, 2011 and 2012 was respectively: 348, 661, 713; embryo donation respectively: 241, 251 and 267) [1]. The largest number of procedures with the donation of oocytes is carried out in Spain (more than 11,000 procedures in 2010). ED procedures are also often carried out in countries such as the Czech Republic, Russia and the United Kingdom [2].

Intrauterine insemination is a procedure which is relatively simple and does not require highly specialized laboratory and medical equipment. For these reasons it is highly used in many clinics and by many gynaecologists. The data for IUI were reported only by 31 clinics. Therefore, the actual scale of use of IUI in infertility treatment in Poland remains unknown. However, the results, based on 14,727 treated cycles that were reported, allow to assess the effectiveness of this method of treatment. The delivery rate per cycle amounted to 8.7% (8.9% in 2011) and was

close to the European average (8.9%) [2]. The success rate of IUI with donor semen was twice higher in comparison to IUI with husband's/partner's semen (delivery rate for IUI-D and IUI-H was 14.1% and 7.9% respectively).

The risk of multiple pregnancy after IUI was lower than in case of treatment using IVF/ICSI (6.2% vs. 15.7%).

The Cross-border reproductive care is an interesting phenomenon that may be observed in Poland. The main reason why patients seek help in our country are legal restrictions in their home countries. Consistently, the majority of couples are from Germany (74.2%), and start the treatment with the donor gametes. In Germany in 2012 the egg donation was prohibited, and the cost of treatment was much higher than in Poland. The reimbursement of in vitro treatment in Germany is accessible only to married couples using their own gametes. Direct neighbourhood is not without significance in selection of Poland, where German couples undergo their treatment. In comparison to the previous year the number of couples from the United Kingdom decreased (8.3 vs. 19.3%) [1]. The reason of this difference is unknown.

Conclusion

The presented SPiN PTG report provides summary of ART procedures carried out in Poland in 2012, their effectiveness and safety. Every year the number of centres participating in reporting and the number of cycles treated with assisted reproductive techniques increases. The effectiveness of treatment in Poland is high, a few percentage points higher than the average for Europe. Conducted strategies are focused not only on the outcome but also on patients' and children's safety (rare cases of severe OHSS; ≤ 2 embryo transfer policy to reduce the risk of multiple pregnancies).

Reported data are the only proof of responsibility and medical consistency for the period preceding the implementation of governmental regulations concerning ART methods (i.e. before November 1, 2015). The main weakness of this report is its optional nature and the lack of follow-up of pregnancies and births.

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