Family Man: SART Male Data

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ASRM Board of Directors, Publications Committee

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MARCH 20-23, 2024
INDIAN WELLS, CA

Disclosures

- Nothing to Disclose

Learning Objectives

- Describe the way SART collects & reports data
- List male factor infertility fields in SART
- Identify how SART data has shaped IVF standards of care

SART Data Collection & Reporting

ASRM

Affiliate Societies within ASRM

SRS SMRU SREI SRBT SART

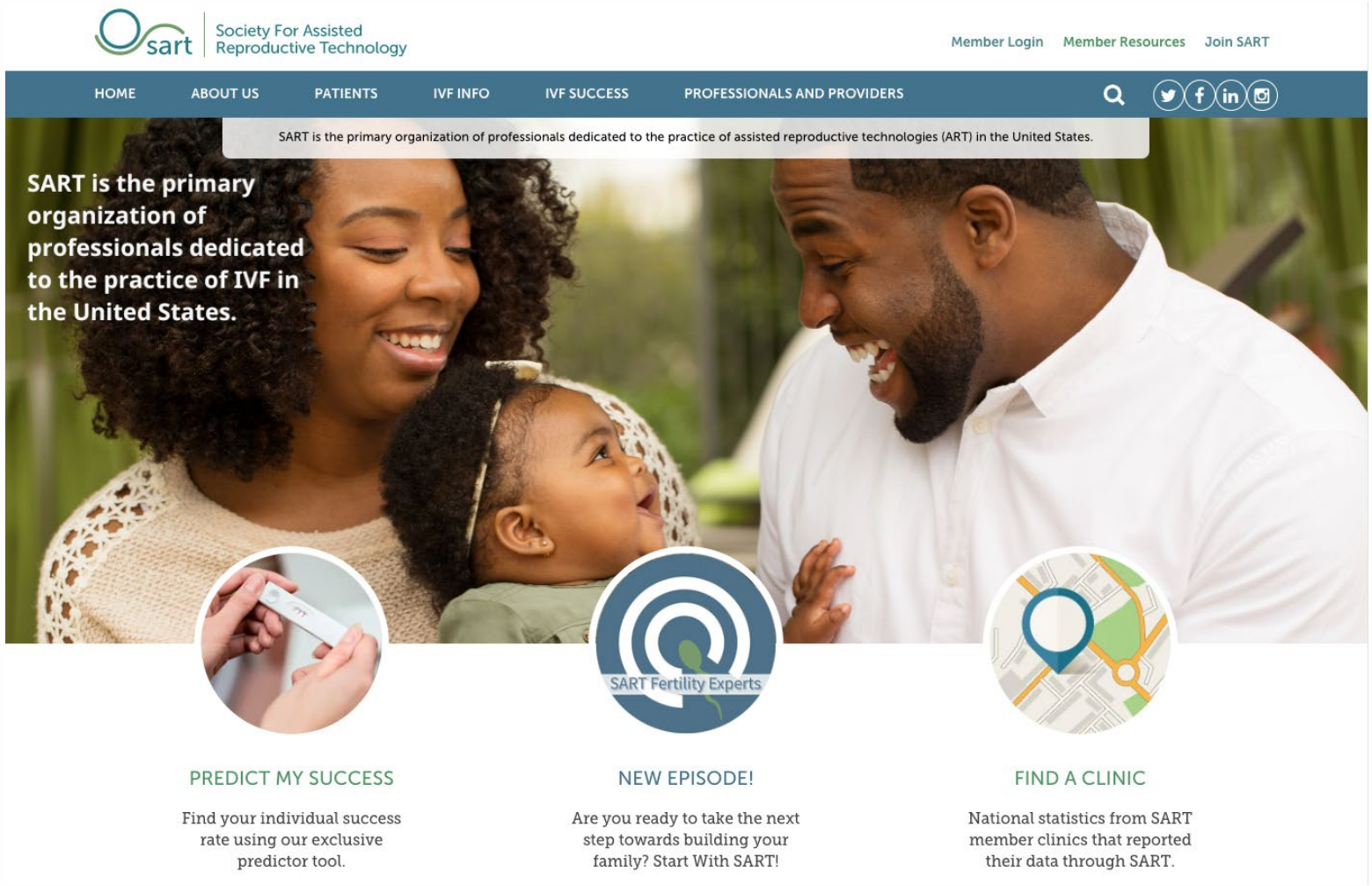
Also within ASRM

- Professional groups for nurses, reproductive lawyers, etc.
- Special interest groups for genetic counselors, artificial intelligence, etc.

SART is Quality

www.sart.org

Start with SART



www.sart.org

What Does SART Do?

Reports IVF outcomes

Sets guidelines for best practices in the field of ART

Reviews patient advocacy and regulatory issues

Assures quality

www.sart.org

Fertility Clinic Success and Certification Act of 1992 (FCSCA)

- The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each Assisted Reproductive Technologies (ART) program report annually to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (CDC)

- Each ART program reports pregnancy outcomes annually

- Each ART program embryo laboratory must be certified by TJC or CAP

Federal Register Notifications (FRNs) from HHS and CDC

2015 FRN

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).
ACTION: Final notice.

2019 FRN

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Clarifications and Corrections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).
ACTION: Notice.

2022 FRN

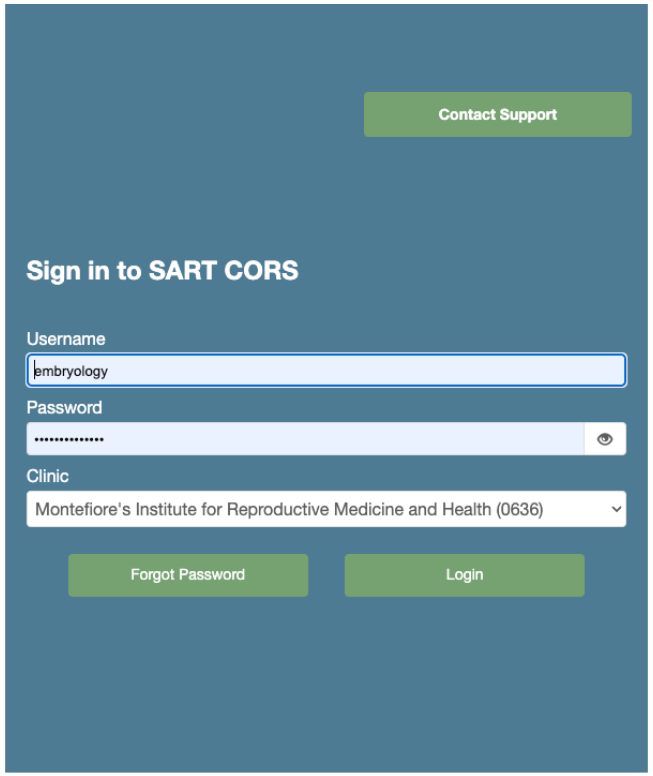
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

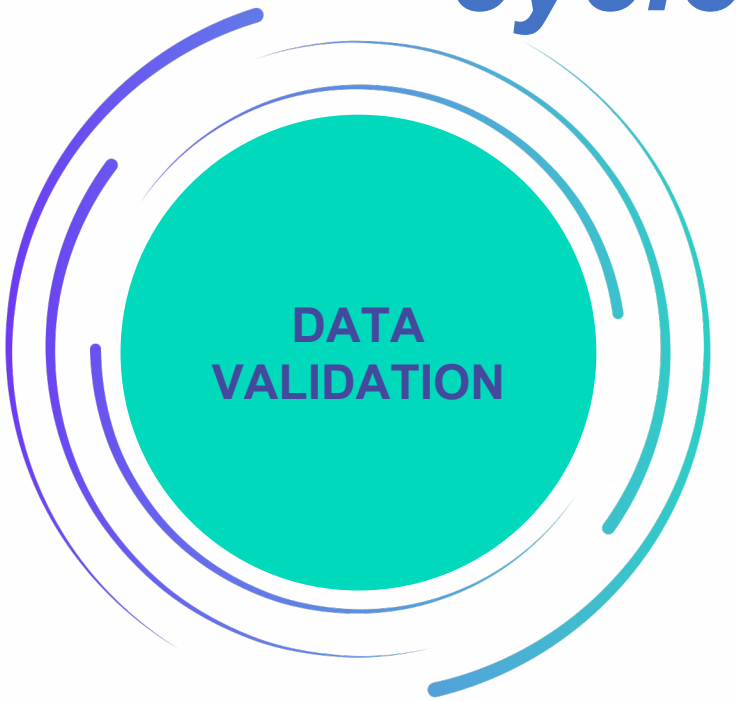
[Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Clarifications and Corrections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).
ACTION: Notice.

SART Clinic Outcome Reporting System (SART CORS)



SART Helps Ensure Accurate reporting of all cycles based on patient stimulation and cycle start



SART's Big Picture Goals

CONTINUE TO ENHANCE SART CLINICAL OUTCOMES REPORTING SYSTEM (SART CORS) TO OPTIMIZE EASE OF USE AND IMPROVE THE QUALITY OF DATA COLLECTED.

MAINTAIN TIMELY ANNUAL REPORTING TO THE CDC AND CONTINUE TO IMPROVE THE CLINIC SUMMARY REPORT (CSR)

BUILD THE SART BRAND SO THAT MEMBER CLINICS, PATIENTS AND POLICYMAKERS ASSOCIATE SART UNIQUELY WITH QUALITY AND SAFETY

ENHANCE THE VALUE THAT SART PROVIDES TO ITS MEMBERS WITH FUNCTIONS SUCH AS THE QUERY ENGINE, QA DASHBOARD, AND CLINIC SEARCH FUNCTION

IMPROVE THE QUALITY OF OUR COMMUNICATIONS AND ENGAGEMENT WITH MEMBER CLINICS

SART 5-year strategic plan was created July 2023

SART Male Factor Infertility Fields

SART CORS Data Entry

Reason for ART

- [x] Male Infertility
  - [ ] Medical Condition
  - [ ] Genetic or chromosomal abnormality
  - [x] Abnormal sperm parameters
    - [ ] Azoospermia, obstructive
    - [ ] Azoospermia, non-obstructive
    - [ ] Oligospermia, severe(< 5 million / mL)
    - [ ] Oligospermia, moderate (5 - 15 million / mL)
    - [ ] Low Motility(<40%)
    - [x] Low Morphology(4%)
    - [ ] Very Severe Male Factor (< 1 million)
  - [ ] Other male factor
- [ ] History of Endometriosis
- [ ] Tubal Ligation (Not Reversed)
- [ ] Tubal Hydrosalpinx (In Place)
- [ ] Other Tubal Disease
- [x] Uterine
  - [ ] Uterine Transplant
- [x] Ovulation Disorders
  - [ ] PCOS
  - [ ] Hypothalamic Amenorrhea
  - [x] Diminished Ovarian Reserve
    - [ ] Premature Ovarian Failure
    - [ ] Turner Syndrome
    - [ ] Other Dim. Ovarian Reserve
  - [ ] Other ovulation disorders
- [ ] Freeze-All (For Fertility Preservation or not)
- [ ] Indication for use of gestational carrier
- [ ] Recurrent pregnancy loss
- [ ] Other
- [ ] Unexplained (clears all diagnoses)

SART CORS Male Infertility Fields

Medical Condition

Significant medical conditions presenting as, or contributing to, male infertility (i.e., hormonal and oxidative dysfunction such as diabetes mellitus, thyroid disease, pituitary adenoma, hypopituitarism, cancer of prostate or testes, retroperitoneal and spinal cord tumors, polycystic kidney disease, varicocele, retrograde ejaculation, infection, inflammation and autoimmunity involving the genitourinary system, etc.).

Genetic Or Chromosomal Abnormality

Presence of a laboratory documented genetic condition known to be associated with male infertility (Y chromosome microdeletion, Klinefelter Syndrome, Cystic Fibrosis etc.

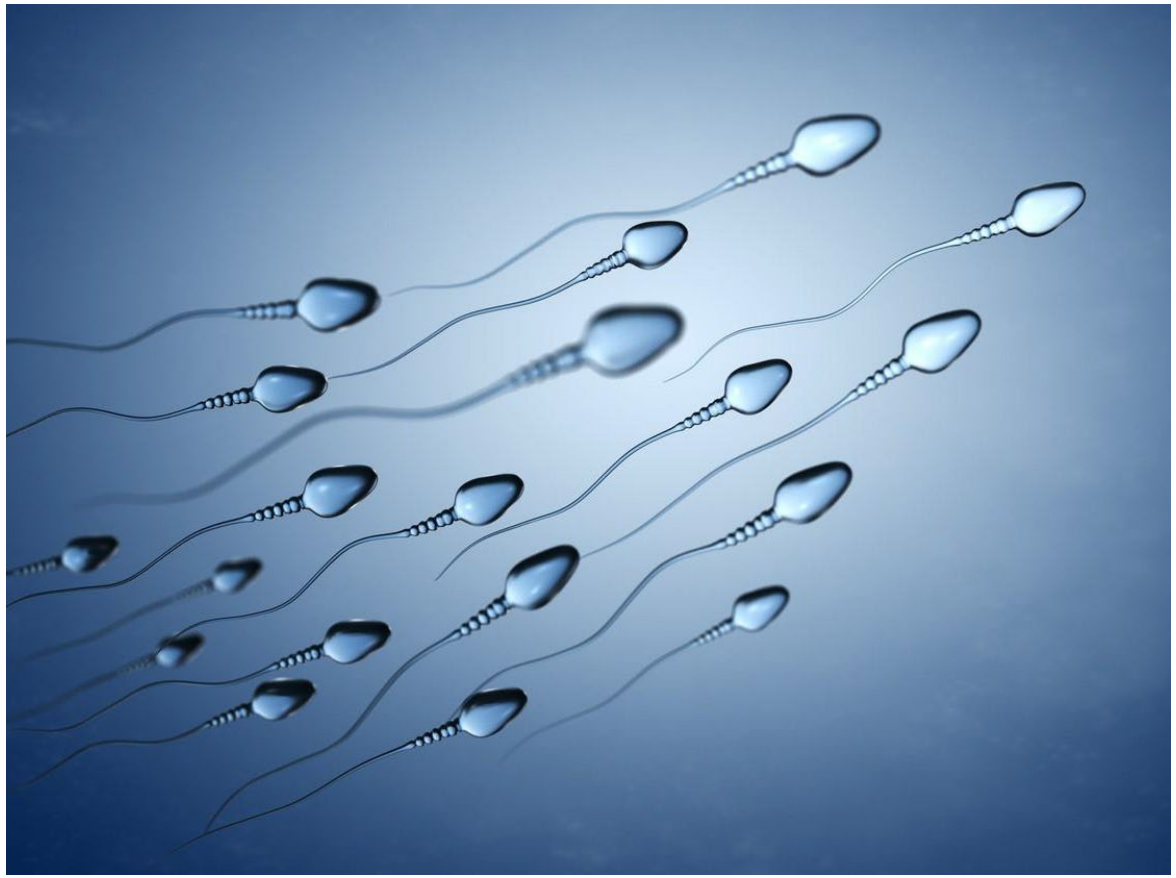
SART CORS Abnormal Sperm Parameters

Azoospermia, Obstructive

Complete absence of sperm from the ejaculate. Obstructive azoospermia may result from epididymal, vasal, or ejaculatory duct pathology. Vasectomy is the most common cause of vasal obstruction. Other causes include severe genitourinary infections, iatrogenic injury during scrotal or inguinal surgical procedures and congenital anomalies.

Azoospermia, Nonobstructive

Abnormal sperm production due to testicular failure, varicoceles, or chromosomal abnormalities such as Y-chromosome microdeletions or karyotypic abnormalities (e.g., Klinefelter syndrome).



SART CORS Abnormal Sperm Parameters

Oligospermia, moderate (5 - 15 million / mL)

5-15 million spermatozoa per mL.

Oligospermia, severe(< 5 million / mL)

Semen with a low concentration of sperm. Severe oligospermia is defined as >=1 to <5 million spermatozoa per mL.

SART CORS Abnormal Sperm Parameters

Low Motility(< 40%)

Sperm motility less than 40%.

Low Morphology(4 %)

Sperm morphology less than 4% normal.

SART CORS Abnormal Sperm Parameters

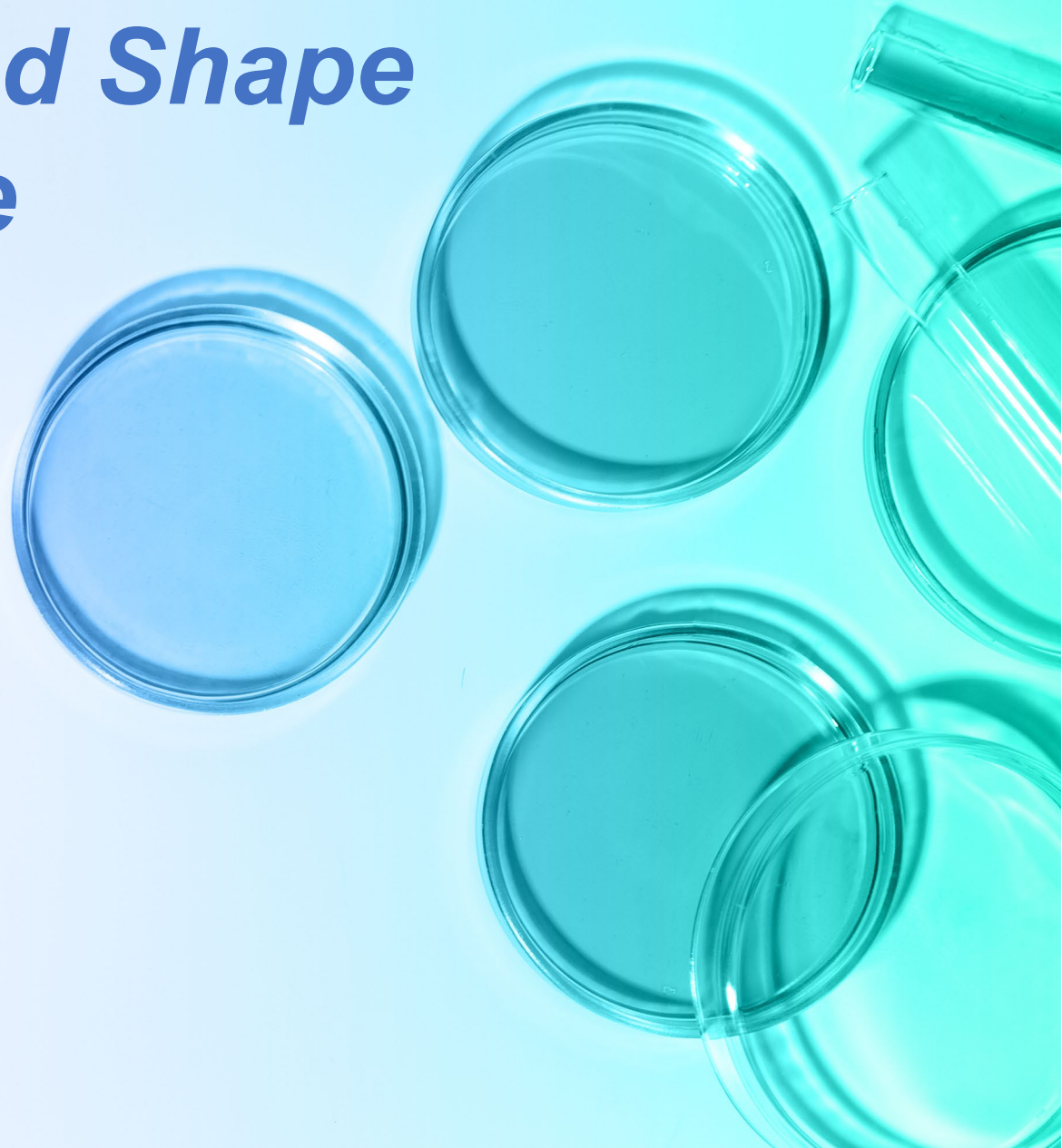
Very Severe Male Factor (< 1 million)

<1 million sperm per ml

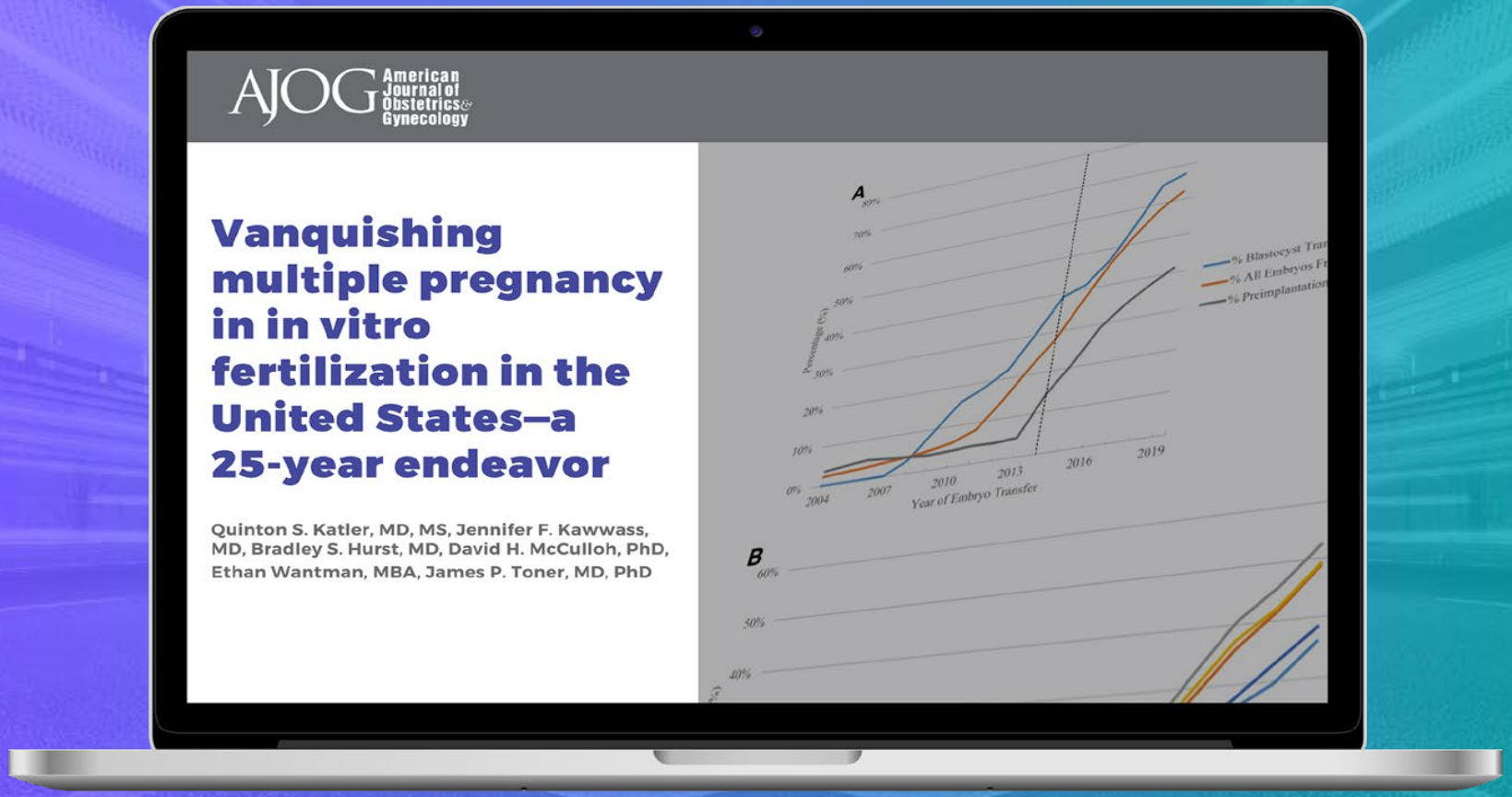
Other Male Factor

Male factor infertility due to other reasons.

SART Data Has Helped Shape IVF Standards of Care



Key to the Vanishing Multiple Pregnancy Rate



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Fewer embryos being transferred

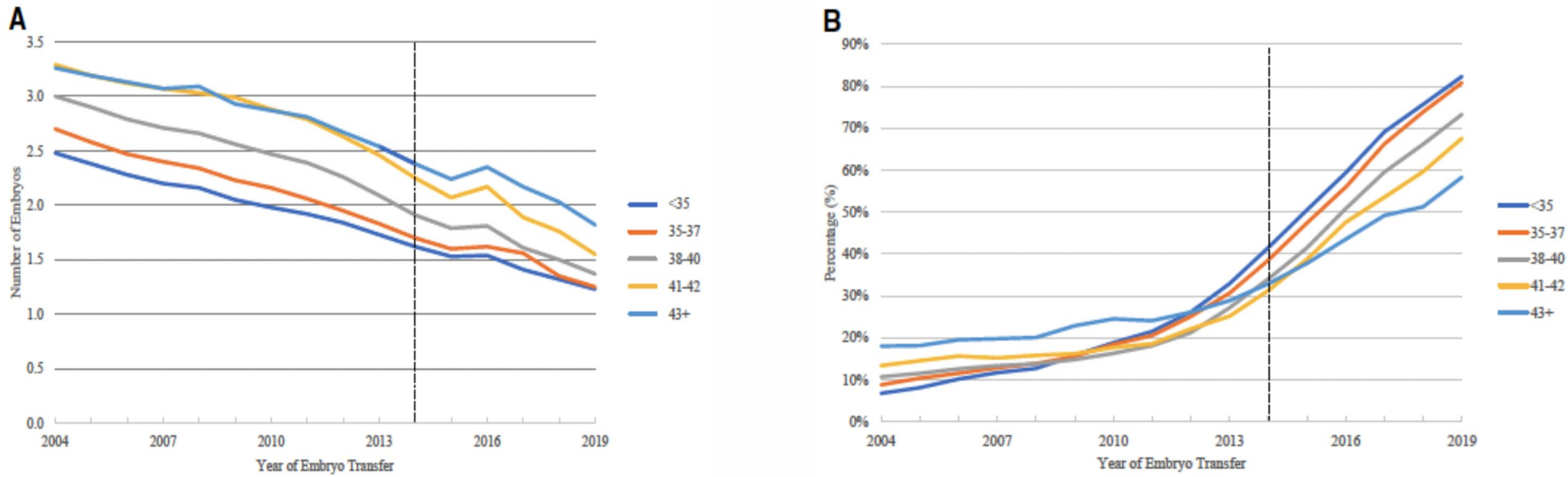

Figure 2

Katler et al, 2022

Fewer multiple births and fewer children born as multiples

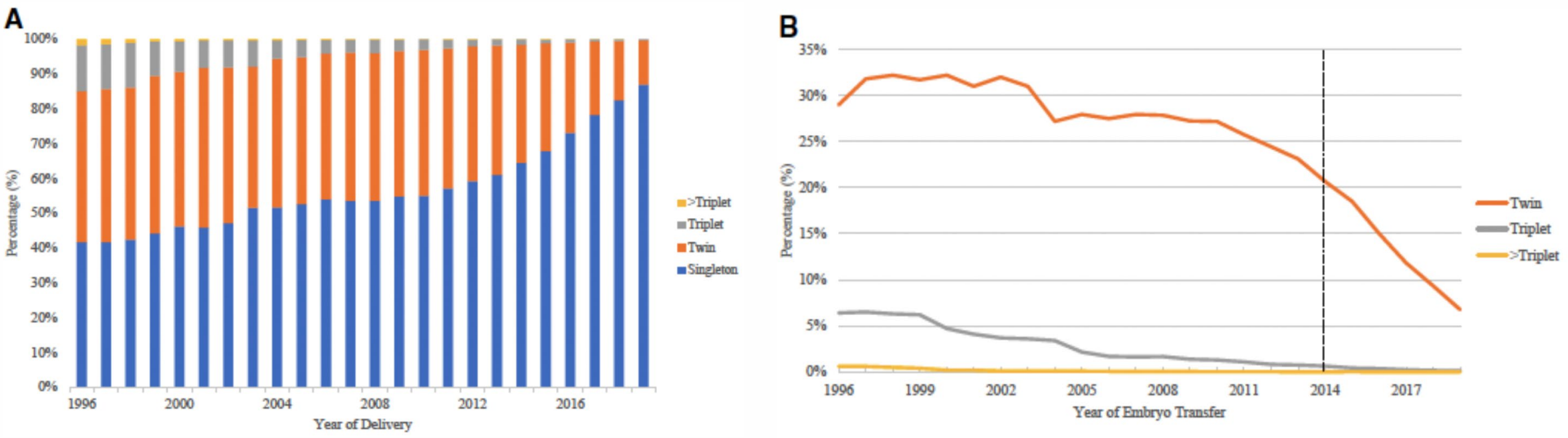

Figure 3

Katler et al, 2022

National study of factors influencing assisted reproductive technology outcomes with male factor infertility

Ajay K. Nangia, M.B.B.S.,[a] Barbara Luke, Sc.D., M.P.H.,[b] James F. Smith, M.D., M.S.,[c] Winifred Mak, M.D., Ph.D.,[d] Judy E. Stern, Ph.D.,[c] and the SART Writing Group

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TABLE 3

Model for treatment outcomes from conventional IVF (non-ICSI) versus ICSI cycles due to male factor infertility only.

Outcome	Use of ICSI	Male factor only—no female factor AOR	95% CI	*P* value
Treatment outcome				
Clinical intrauterine pregnancy	ICSI—none	1.00	Reference	
vs. not pregnant or other[a]	ICSI—some or all	0.93	0.87–0.99	.03
Pregnancy outcome				
Live birth vs. fetal death or	ICSI—none	1.00	Reference	
stillbirth	ICSI—some or all	0.91	0.79–1.04	.16

Note: Model adjusted for woman's age, male and female race/ethnicity, day of ET, and number of embryos transferred. In all groups, only ejaculated sperm was used. ICSI = intracytoplasmic sperm injection; AOR = adjusted odds ratio; CI = confidence interval.

[a] Other includes biochemical, ectopic, and heterotopic.

Nangia. Male factor infertility and ART outcomes in the USA. Fertil Steril 2011.

Nangia et al, 2011

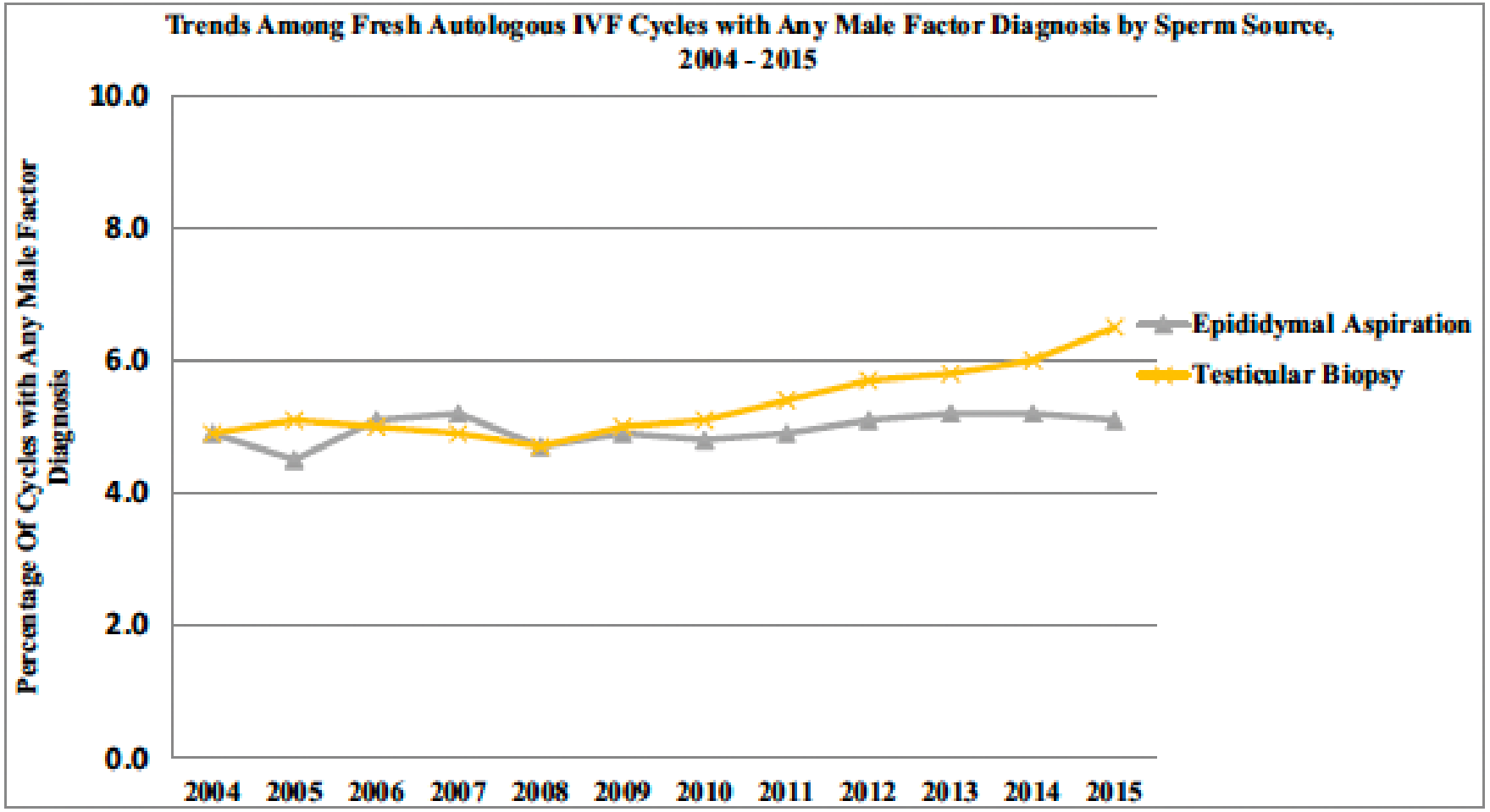
Journal of Assisted Reproduction and Genetics (2018) 35:1229–1237
https://doi.org/10.1007/s10815-018-1178-5

ASSISTED REPRODUCTION TECHNOLOGIES

Surgically acquired sperm use for assisted reproductive technology: trends and perinatal outcomes, USA, 2004–2015

Jennifer F. Kawwass[1,2] · Jeani Chang[2] · Sheree L. Boulet[2] · Ajay Nangia[3] · Akanksha Mehta[1,4] · Dmitry M. Kissin[1,2]

Fig. 1 Trends among fresh autologous IVF cycles with a male factor diagnosis—percentage of cycles with surgically acquired sperm, 2004–2015. *IVF in vitro fertilization, $p < 0.05$ for both epididymal and testicular sperm



* IVF= *in vitro* fertilization, p<0.05 for both epididymal and testicular sperm

Kawwass et al, 2018

The impact of using donor sperm in assisted reproductive technology cycles on perinatal outcomes

Bo Yu, M.D., M.S.,[a,*] Rani Fritz, D.O., Ph.D.,[b,c,*] Xianhong Xie, Ph.D.,[d] Abdissa Negassa, Ph.D.,[d] Sangita Jindal, Ph.D.,[b,c] Mario Vega, M.D.,[b,c] and Erkan Buyuk, M.D.[b,c]

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TABLE 2

Comparison of perinatal outcomes between donor and partner sperm ART cycles.

Outcome	Donor sperm (n = 2,123)	Partner sperm (n = 42,799)	Unadjusted effect estimate (95% CI)	Adjusted effect estimate (95% CI)[a]
Miscarriage (%)	554 (26.1)	9,052 (21.2)	1.32 (1.19, 1.45)	0.997 (0.898, 1.108)
Gestational age (wk), mean ± SD	38.9 ± 2.2	38.8 ± 2.2	0.12 (−0.001, 0.23)	0.10 (−0.02, 0.22)
Preterm birth (%)	167 (10.8)	3,775 (11.4)	0.96 (0.82, 1.12)	0.94 (0.78, 1.33)
Very preterm birth (%)	53 (3.4)	1,104 (3.3)	1.06 (0.81, 1.39)	0.99 (0.73, 1.14)
Birthweight (g), mean ± SD	3,292 ± 601	3,233 ± 592	59.32 (29.28, 89.36)	42.81 (14.68, 70.94)
Low birthweight (%)	127 (8.4)	2,953 (9.0)	0.93 (0.78, 1.11)	0.87 (0.71, 1.06)
Very low birthweight (%)	21 (1.4)	523 (1.6)	0.89 (0.55, 1.45)	0.82 (0.48, 1.39)

[a] Models were adjusted for maternal age, race, body mass index, smoking status, gravidity, history of preterm birth, maximum FSH, blastocyst transfer, total embryo transferred, and etiology of infertility.

Yu. Donor sperm ART cycle perinatal outcomes. Fertil Steril 2018.

Yu et al, 2018

Intracytoplasmic sperm injection (ICSI) for non–male factor indications: a committee opinion

Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology

American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, Birmingham, Alabama

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CONCLUSIONS

- ICSI without male factor infertility may be of benefit for select patients undergoing IVF with preimplantation genetic testing for monogenic disease and previously cryopreserved oocytes.
- The additional cost burden of ICSI for non–male factor indications, where data on improved live-birth outcomes over conventional insemination are limited or absent, must be considered.

ASRM PC 2020 ICSI

Intracytoplasmic sperm injection vs. conventional in vitro fertilization in patients with non-male factor infertility

Aya Iwamoto, M.S., M.D., Bradley J. Van Voorhis, M.D., Karen M. Summers, M.P.H., Amy Sparks, Ph.D., and Abigail C. Mancuso, M.D.

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TABLE 2

Cumulative live birth and miscarriage rates among day 5 transfers using intracytoplasmic sperm injection vs. conventional in vitro fertilization.

	Without genetic testing (N = 22,314)				With PGT-A (N = 4,445)			
Outcome	**ICSI**	**cIVF**	**RR (95% CI)**	**ARR (95% CI)[a]**	**ICSI**	**cIVF**	**RR (95% CI)**	**ARR (95% CI)[a]**
CLBR	60.9%	64.3%	0.95 (0.93–0.97)	0.99 (0.99–1.00)	64.7%	69.0%	0.94 (0.88–0.99)	0.97 (0.93–1.01)
Miscarriage rate	11.3%	11.8%	0.96 (0.89–1.03)	1.00 (0.94–1.06)	9.0%	10.2%	0.882 (0.64–1.12)	0.95 (0.72–1.24)

ARR = adjusted risk ratio; CI = confidence interval; cIVF = conventional in vitro fertilization; CLBR = cumulative live birth rate; ICSI = intracytoplasmic sperm injection; PGT-A = preimplantation genetic testing for aneuploidy; RR = risk ratio.

[a] Adjusted for age, body mass index, and the number of oocytes retrieved.

Iwamoto. ICSI vs. cIVF in non-male infertility. Fertil Steril 2022.

Iwamoto et al, 2022

Comparing reproductive outcomes between conventional in vitro fertilization and nonindicated intracytoplasmic sperm injection in autologous embryo transfer cycles: a Society for Assisted Reproductive Technology Clinic Outcome Reporting System Study

Julian A. Gingold, M.D., Ph.D.,[a] Haotian Wu, Ph.D.,[b] Harry Lieman, M.D.,[a] Manvinder Singh, M.D.,[a] and Sangita Jindal, Ph.D., H.C.L.D.[a]

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TABLE 3

Odds ratios of IVF outcomes by ICSI usage and stratified by male infertility.

Subgroup		Live Birth OR	Live Birth 95% CI	Live Birth *P* Value	Clinical Pregnancy OR	Clinical Pregnancy 95% CI	Clinical Pregnancy *P* Value	Spontaneous Abortion OR	Spontaneous Abortion 95% CI	Spontaneous Abortion *P* Value
Diagnosed male infertility										
Fresh—no PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI	1.45	1.32, 1.59	<.001	1.52	1.4, 1.66	<.001	1.56	1.28, 1.9	<.001
Frozen—any PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI	1.10	0.92, 1.31	.29	1.17	0.98, 1.4	.09	1.15	0.83, 1.58	.40
Frozen—no PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI	1.00	0.89, 1.13	.99	0.96	0.86, 1.08	.50	0.91	0.76, 1.08	.26
No male infertility										
Fresh—no PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI	0.80	0.78, 0.83	<.001	0.79	0.77, 0.82	<.001	0.84	0.79, 0.89	<.001
	2012/2020 guidelines[a]									
	Indicated ICSI	0.85	0.7, 1.03	.09	0.85	0.71, 1.01	.07	0.93	0.67, 1.29	.66
	Nonindicated ICSI	0.80	0.78, 0.83	<.001	0.79	0.77, 0.82	<.001	0.84	0.79, 0.89	<.001
Frozen—any PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI/indicated ICSI by 2012 guidelines	0.99	0.94, 1.04	.60	1.02	0.97, 1.08	.46	1.11	1.01, 1.22	.03
	2020 guidelines									
	Indicated ICSI	0.99	0.89, 1.1	.79	1.02	0.92, 1.14	.70	1.15	0.95, 1.39	.15
	Nonindicated ICSI	0.99	0.93, 1.04	.58	1.02	0.97, 1.08	.47	1.11	1.01, 1.22	.03
Frozen—no PGT	IVF without ICSI	Ref			Ref			Ref		
	All ICSI	1.02	0.98, 1.07	.29	1.04	0.99, 1.08	.10	1.02	0.96, 1.09	.56

Note: All models adjusted for age, BMI, male infertility (yes/no), female infertility [binary categories for PCOS or ovulatory disorders, tubal factors or endometriosis, DOR, or other factors (uterine or hypothalamic amenorrhea)], and prior IVF live birth (0/1). Models for fresh cycles further adjusted for number of total retrieved oocytes. No individuals in the Frozen—any PGT group had DOR. Effects of indicated ICSI for patients with no male infertility could not be estimated in the Frozen—no PGT group because of insufficient sample size.

BMI = body mass index; CI = confidence interval; DOR = diminished ovarian reserve; ICSI = intracytoplasmic sperm injection; IVF = in vitro fertilization; OR = odds ratio; PCOS = polycystic ovarian syndrome; PGT = preimplantation genetic testing.

[a] For cycles not utilizing PGT, the 2012/2020 guidelines are equivalent.

Gingold. IVF vs. nonindicated ICSI in SART CORS. Fertil Steril Rep 2023.

Gingold et al, 2024

In Summary

- SART sets safety standards and practice metrics for IVF in the US
- Evidence-based studies from SART CORS help define IVF practice in the US
- Reporting our IVF outcomes has advanced the quality of care in the US
- Male data in SART is waiting to be mined!

Thank You

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