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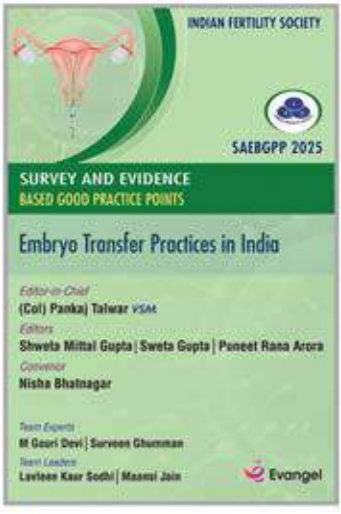
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SAEBGPP 2025

Survey and Evidence Based Good Practice Points

Evaluation of Current Practices of Preimplantation Genetic Testing Amongst IVF Clinicians in India

Independent Ethical Committee: F.1/IEC/IFS/2025/No.26

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SAEBGPP 2025

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Dedicated to

All gynecologists of India—those who continue to serve with compassion, courage, and commitment; those who balance science with empathy; those who stand by their patients through hope, uncertainty, and healing; and those who strive every day to raise the standards of women's health and reproductive care in our country.

Your tireless efforts inspire this entire initiative.

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Preface

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The SAEB (Survey and Evidence-Based) Good Practice Points initiative was conceived with the vision of bringing together clinicians, embryologists, researchers, and educators across India to create practical, implementable, and ethically sound guidelines that address real-world challenges in reproductive medicine. Each chapter in this compendium represents months of dedicated teamwork, data collection, expert deliberation, and collaborative refinement.

An important driving force behind this initiative has been the vision of the IFS President, who recognised the prevailing lacunae and knowledge gaps arising from the absence of India-specific recommendations. This endeavour reflects the commitment to develop guidance that is rooted in our own population data, clinical realities, and diversity of practice settings.

The strength of this work lies in its collective wisdom. By combining survey-driven insights with a rigorous evidence-based approach, we have attempted to bridge the gap between everyday clinical practice and evolving scientific knowledge. These GPP documents are not meant to replace existing guidelines; rather, they aim to complement them by offering context-specific recommendations tailored to the Indian ART landscape.

It is our hope that this consolidated effort will support clinicians in making informed decisions, encourage uniformity of care, and ultimately contribute to improved patient outcomes. We extend our gratitude to everyone who contributed to this initiative and made this work possible.

Acknowledgments

We extend our heartfelt appreciation to all the experts, clinicians, embryologists, and young team members who worked tirelessly on each of the eleven SAEB GPP projects. Your commitment to scientific rigor, your enthusiasm for learning, and your willingness to collaborate have been the foundation of this initiative.

We gratefully acknowledge the unwavering support of the team leaders and national coordinators who guided each group with clarity, patience, and vision. The completion of the surveys, the collection of adequate sample sizes, the detailed discussions, drafting, redrafting, and finalization of recommendations would not have been possible without your leadership.

We thank the reviewers, statisticians, and mentors who provided constructive feedback at every stage, ensuring that each chapter meets the highest academic and practical standards. Special appreciation is extended to the editorial and organizational teams whose behind-the-scenes efforts—coordination, communication, formatting, plagiarism checks, and preparation of final deliverables—were indispensable.

To every participant who contributed time, expertise, and passion: this work stands as a testament to your dedication to improving ART practice in India.

We are extremely thankful to Meyer Organics Pvt Ltd for providing academic support for this project.

Contents

Evaluation of Current Practices of Preimplantation Genetic Testing Amongst IVF Clinicians in India

INTRODUCTION

Preimplantation genetic testing (PGT) stands as one of the most significant technological advancements in assisted reproductive technology (ART) over the last two decades. By offering the ability to analyze the genetic health of an embryo prior to implantation, PGT has revolutionized the management of genetic disease transmission (PGT-M), structural chromosomal rearrangements (PGT-SR), and, most contentiously, age-related aneuploidy (PGT-A). For couples undergoing *in vitro* fertilization (IVF), PGT represents a powerful tool for reducing miscarriage rates, improving implantation success, and ensuring the delivery of a healthy, unaffected child.

Globally, the application of PGT is guided by continually evolving, and often conflicting, international consensus statements and clinical guidelines. The debates surrounding PGT-A—particularly its utility for patients with advanced maternal age (AMA), recurrent pregnancy loss (RPL), or repeated implantation failure (RIF)—underscore the field's complexity and the necessity for clinicians to constantly re-evaluate their protocols against the latest evidence.

The Indian landscape of reproductive medicine presents a unique context. The country's burgeoning IVF sector is characterized by a high volume of cycles, rapid technological adoption, and diverse patient demographics, including a high prevalence of specific single-gene disorders due to regional factors. Navigating the ethical, technical, and regulatory challenges (such as the regulation against non-medical sex selection) requires not only access to advanced technology but also a clear, evidence-based strategy for its clinical application. However, data on the

actual implementation and rationale behind PGT decisions within Indian clinics often remains siloed, creating a vital knowledge gap between global best practice and local realities.

To address this gap, this study employs a rigorous, evidence-based methodology, centered on 19 targeted PICO (Population, Intervention, Comparison, Outcome) questions. The PICO framework is the cornerstone of modern evidence-based medicine, ensuring that each survey item is specifically designed to elicit responses regarding clinical decision-making across key scenarios, including:

- The use of PGT-A in specific high-risk populations, such as women with AMA or unexplained RPL.
- The practical management and disclosure strategies for complex genetic results, such as mosaicism.
- The utilization of PGT-M for prevalent monogenic conditions and the complexities of probe design.
- The nascent, but critical, ethical considerations surrounding newer techniques like Polygenic Risk Scores (PRS) and noninvasive PGT (niPGT).

By collecting and analyzing responses across these 19 clinical domains, this survey aims to map the prevailing PGT practices among IVF clinicians across India. The findings will provide a crucial benchmark, highlighting areas where Indian practice aligns strongly with established international guidelines and, equally important, identifying domains where significant variations, research gaps, or conflicting evidence necessitate further consensus-building and education. Ultimately, this research seeks to inform the development of context-specific, evidence-driven guidelines to elevate the standard of care in PGT for the benefit of infertile couples nationwide. Ethical clearance was obtained from the institutional ethics committee. The minimum statistically significant sample size required for the survey was 380 responses, and we successfully received 507 responses.

PICO 1: DOES PREIMPLANTATION GENETIC TESTING FOR WOMEN WITH ADVANCED MATERNAL AGE (AMA) IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

In women of advanced maternal age undergoing IVF, PGT-A *may be considered* to enhance embryo selection and improve live birth rates, but its use should be individualized rather than routine. Comprehensive chromosome screening methods are preferred when applied.

Summary of Evidence

A systematic review and meta-analysis of 9 Randomized Controlled Trials showed that application of comprehensive chromosome screening (3 trials) had a beneficial effect of PGT-A in women of AMA (>35 years) compared with FISH (6 trials). Moreover, blastocyst biopsy seemed to be associated with a better outcome than polar body biopsy and cleavage-stage biopsy.[1] A systematic review and meta-analysis of 5 Randomized Controlled Trials (RCTs) and 14 nonrandomised studies stated that PGT-A improved the efficiency of ART, increasing clinical pregnancy and LBR, especially in women of AMA.[2] An observational cohort study showed that PGT-A had no major impact on Cumulative live birth rate per egg retrieval in women with advanced maternal age (38-44 years).[3]

Research Gaps

More high-quality RCTs needed, and there is heterogeneity in studies (differences in study populations, PGT-A techniques and outcome measures).

Survey Results from India (Fig. 1)

- 50.99% (n = 257) of respondents offered PGT-A in cases where maternal age is over 35 years of age.
- 46.83% (n = 236) respondents offered PGT–A in cases where maternal age is over 37 years.
- 2.18% (n = 11) of respondents do not offer PGT-A in cases of advanced maternal age.

Choices	Percentage	Count
To all patients above the age of 35 years	50.99%	257
Above 37 years	46.83%	236
None of the above	2.18%	11
	Total	504
	Unanswered	3

Fig. 1: PGT-A Offering among Indian clinicians

Integration with Evidence and Key Good Practice Point

Indian clinicians offered PGT-A in 50.99% of cases where maternal age is more than 35 years, while in women over 37 years, uptake was 46.83% aiming to improve the chances of achieving a pregnancy. This practice is in alignment with current evidence supporting a tailored approach rather than universal application.

PICO 2: DOES PREIMPLANTATION GENETIC TESTING FOR COUPLES WITH RECURRENT MISCARRIAGES IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

PGT-A may be considered, but not universally, with the use of PGT-A in RPL (≥2 recurrent pregnancy loss) should be individualized, taking into account maternal age, embryo availability, cause of RPL (unexplained vs known), and patient preference.

Summary of Evidence

The retrospective study suggests that preimplantation genetic testing for euploid embryo selection may provide significant benefit to couples with recurrent pregnancy loss undergoing IVF, especially in the setting of advanced maternal age.[4] The systematic review and meta-analysis of 17 retrospective,1 prospective, and 1 RCT studies suggest that PGT-A enhances LBR (Live Birth Rate) per transfer and per patient in unexplained RPL.[5]

Research Gaps

There is a lack of high-quality RCTs and heterogeneity in patient populations.

Survey Results from India (Fig. 2)

- 54% (n = 273) of respondents reported considering PGT-A in cases of RPL for women with advanced maternal age (AMA).
- 38% (n = 192) of respondents used PGT-A in cases of RPL for women with both AMA and poor ovarian reserve.
- 6.75% (n = 34) of respondents used PGT-A in cases of RPL irrespective of patient age.

- Only 1% (n = 5) of respondents used PGT-A for patients with poor ovarian reserve only.

Choices	Percentage	Count
Age > 38 years	54.17%	273
Both AMA and poor ovarian reserve	38.10%	192
All ages	6.75%	34
Poor ovarian reserve	0.99%	5
	Total	**504**
	Unanswered	3

Fig. 2: Distribution of choices (total=504)

Integration with Evidence and Good Practice Points

The Indian survey results overwhelmingly indicate that PGT-A is considered an intervention primarily for high-risk RPL cases, specifically those involving advanced maternal age (82.3% usage when including those with poor ovarian reserve). This suggests a regional practice that is mostly in line with international recommendations to individualize treatment based on maternal age.

PICO 3: DOES PREIMPLANTATION GENETIC TESTING FOR COUPLES WITH RECURRENT IMPLANTATION FAILURE (RIF) IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

The routine use of PGT-A is not recommended for patients with RIF.

Summary of Evidence

The systematic review and meta-analysis of two RCTs and three observational studies failed to show an improvement in both clinical pregnancy and LBR in women with RIF who underwent PGT-A.[6]

Research Gaps

More high-quality RCTs required.

Survey Results From India (Fig. 3)

- 47.12% (n = 211) of respondents used PGT-A in patients with implantation failure following 1 failed In vitro fertilization (IVF) cycle.
- 39.12% (n = 196) of respondents offered PGT-A in patients with implantation failure with a history of AMA with 1 failed IVF cycle.
- 11.98% (n = 60) of respondents do not recommend PGT-A in patients with RIF.
- 6.79% (n = 34) of respondents offered PGT-A in patients with RIF with a history of 3 failed IVF cycles.

Choices	Percentage	Count
After one failed cycle	42.12%	211
AMA + 1 failed cycle	39.12%	196
None of the above	11.98%	60
3 failed cycles	6.79%	34
	Total	501
	Unanswered	6

Fig. 3: PGT-A Use in patients with implantation failure and RIF

Integration with Evidence and Key Good Practice Point

Survey results revealed that 47.12% (n = 211) of respondents offered PGT-A in patients with implantation failure after one failed IVF cycle, and 39.12% (n = 196) offered PGT-A in patients with implantation failure associated with advanced maternal age after one failed IVF cycle. Only 6.79% (n = 34) offered PGT-A in patients with recurrent implantation failure (RIF) after three failed IVF cycles, while 11.98% (n = 60) did not recommend PGT-A in RIF. Current evidence indicates that routine use of PGT-A is not recommended in RIF, as it does not significantly improve cumulative live birth rates, although it may reduce miscarriage risk in

selected subgroups. However, the survey findings suggest that many respondents use PGT-A earlier than evidence supports, highlighting a gap between clinical practice and guideline-based recommendations.

PICO 4: DOES PREIMPLANTATION GENETIC TESTING FOR GOOD-PROGNOSIS COUPLES WITH SUBFERTILITY IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

Preimplantation genetic testing for aneuploidy (PGT-A) is not recommended for routine use in good-prognosis subfertile couples, particularly in younger women with normal ovarian reserve and multiple embryos available.

Summary of Evidence

A retrospective analysis showed that LBR in the PGT-A group was higher in all ages except in women <35 years old (48.7% vs. 41.7%, $p < 0.001$).[7] A systematic review and meta-analysis of 5 Randomized Controlled Trials (RCTs) and 14 nonrandomised studies[2] stated that PGT-A improved the efficiency of ART (Assisted Reproductive Techniques), increasing clinical pregnancy and LBR (Live Birth Rate), especially in women of AMA and those with a poor prognosis; however, no benefits were demonstrated when applied to younger women.[2] A Systematic Review and Meta-analysis (9 RCTs) failed to show improvement in OPRs (Ongoing Pregnancy Rates) using PGT-A in all age groups, <35 years old, and ≥35 years old. There was also no significant difference in CPRs (clinical Pregnancy Rates) in any group.[8]

Research Gaps

There are heterogeneous definitions of "good prognosis" and RCT populations.

Survey Results from India (Fig. 4)

- 89.62% (n = 449) did not offer PGT-A in good prognosis patients with subfertility.
- 8.98% (n = 50) offered PGT-A in good prognosis patients with subfertility with the aim of reducing time to pregnancy.
- 0.2% (n = 1) offered PGT-A in good prognosis patients with subfertility with no prior IVF treatment.
- 0.2% (n = 1) offered PGT-A in good prognosis patients with subfertility with an age of less than 35 years.

Choices	Percentage	Count
No	89.62%	449
Reduce time to pregnancy	8.98%	45
Yes, If yes, do you offer PGT-A	0.80%	4
Yes/No If yes, do you offer PGT-A	0.20%	1
No prior IVF treatment	0.20%	1
Age < 35 years	0.20%	1
	Total	501
	Unanswered	6

Fig. 4: PGT-A offering in good prognosis with subfertility patients

Integration with Evidence and Key Good Practice Point

Survey findings from India showed that 89.62% of clinicians did not offer PGT-A in good-prognosis patients with subfertility, highlighting limited clinical endorsement in this population. This aligns with international evidence, which demonstrates that PGT-A does not improve cumulative live birth rates in good-prognosis patients.

PICO 5: DOES PREIMPLANTATION GENETIC TESTING FOR COUPLES IMPROVE THE UTILIZATION OF ELECTIVE SINGLE EMBRYO TRANSFER (eSET)?

Recommendation

Preimplantation genetic testing for aneuploidy (PGT-A) is not recommended for routine use to improve the utilisation of elective single embryo transfer (eSET).

Summary of Evidence

A closed cohort study of 678 FET cycles showed that transfer of a single vitrified-warmed blastocyst maintains live birth rates, while decreasing multiple pregnancies.[9]

Research Gaps

More high-quality RCTs required.

Survey Results from India (Fig. 5)

- 79.72% (n = 401) of respondents considered PGT-A prior to elective single embryo transfer (eSET) only in rare cases.
- 17.30% (n = 87) of respondents reported that they sometimes considered PGT-A prior to elective single embryo transfer (eSET).
- 1.79% (n = 9) of respondents reported offering PGT-A prior to elective single embryo transfer (eSET) often.
- 1.19% (n = 6) of respondents reported that they always considered PGT-A prior to elective single embryo transfer (eSET).

Choices	Percentage	Count
Rarely	79.72%	401
Sometimes	17.30%	87
Often	1.79%	9
Always	1.19%	6
	Total	503
	Unanswered	4

Fig. 5: PGT-A-consideration prior to eSET (elective single embryo transfer)

Integration with Evidence and Key Good Practice Point

The majority of Indian clinicians (79.72%, n = 401) reported considering PGT-A before eSET only in rare cases, while a smaller proportion (17.30%, n = 87) used it sometimes. Very few reported offering it often (1.79%, n = 9) or always (1.19%, n = 6). These findings highlight that in clinical practice, PGT-A prior to eSET is largely reserved for highly selective situations, aligning with current international guidelines discouraging its routine application in good-prognosis patients.

PICO 6: DOES PREIMPLANTATION GENETIC TESTING FOR MEN WITH ADVANCED PATERNAL AGE (APA) IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

The draft recommendation would suggest that preimplantation genetic testing for aneuploidy (PGT-A) is not recommended solely on the basis of advanced paternal age.

Summary of Evidence

The systematic review and meta-analysis of 6 retrospective non-randomized controlled studies found no association between APA (>40 years) and higher overall aneuploidy rates in day 5/6 embryos.[10] A retrospective cohort study showed no correlation between APA (>40 years) and higher aneuploidy rates.[11]

Research Gaps

Lack of Randomized Controlled Trials (RCTs), and there is no clear threshold for "Advanced" Paternal Age.

Survey Results from India (Fig. 6)

- A total of 39.64% (n = 199) of respondents do not consider PGT-A in cases of advanced paternal age.
- 33.27% (n=167) of respondents reported considering PGT-A in cases where paternal age was greater than 50 years.
- 17.73% (n= 89) of respondents considered PGT-A in cases where paternal age was more than 45 years.
- 9.36% (n= 47) of respondents considered PGT-A in cases where paternal age was more than 40 years.

Choices	Percentage	Count
None of the above	39.64%	199
> 50 years	33.27%	167
> 45 years	17.73%	89
> 40 years	9.36%	47
	Total	**502**
	Unanswered	5

Fig. 6: Consideration of PGT-A in cases of advanced paternal age

Integration with Evidence and Key Good Practice Point

Current evidence does not support the routine use of preimplantation genetic testing for aneuploidy (PGT-A) solely on the basis of advanced paternal age, as

paternal age has a less pronounced impact on embryo aneuploidy compared with maternal age. Reflecting this, the survey showed that 39.64% (n = 199) of respondents do not consider PGT-A in cases of advanced paternal age, while 33.27% (n = 167) reported considering it when paternal age exceeds 50 years. These findings indicate that although some clinicians apply paternal age thresholds, the majority do not use paternal age alone to guide PGT-A, which aligns with current evidence and guideline recommendations.

PICO 7: IS THE USE OF PREIMPLANTATION GENETIC TESTING RECOMMENDED FOR DONOR OOCYTE CYCLES?

Recommendation

Routine use of preimplantation genetic testing for aneuploidy (PGT-A) is not recommended in IVF cycles utilizing donor oocytes.

Summary of Evidence

A retrospective paired cohort study showed that PGT-A testing in donor oocyte-recipient cycles does not improve the chance for live birth nor decrease the risk for miscarriage in the first transfer cycle but does increase cost and time for the patient.[12] Retrospective cohort study showed that preimplantation genetic testing for aneuploidy in fresh oocyte donor cycles was associated with decreased live birth rates and cumulative live birth rates, whereas effects on frozen-thawed oocyte donor cycles were clinically negligible.[13]

Research Gaps

Lack of Randomized Controlled Trials (RCTs) and high euploidy rates in donor cycles.

Survey Results from India (Fig. 7)

- 79.68% (n = 400) of respondents do not consider PGT-A in donor egg cycles.
- 14.34% (n = 72) of respondents considered PGT-A in donor egg cycles with a history of RIF.
- 4.38% (n = 22) of respondents considered PGT-A in donor egg cycles with a history of RPL.
- 1.59% (n = 8) respondents considered PGT-A in donor egg cycles for elective single embryo transfer (eSET).

Choices	Percentage	Count
None of the above	79.68%	400
RIF	14.34%	72
RPL	4.38%	22
SET	1.59%	8
	Total	502
	Unanswered	5

Fig. 7: Consideration of PGT-A in donor egg cycels

Integration with Evidence and Key Good Practice Point

Current evidence suggests that routine use of preimplantation genetic testing for aneuploidy (PGT-A) is not recommended in IVF cycles utilizing donor oocytes, as donor eggs are generally from younger, fertile donors with a lower risk of aneuploidy. Consistent with this, the survey showed that the majority of respondents (79.68%, n = 400) do not consider PGT-A in donor egg cycles. Among those who do, 14.34% (n = 72) reported considering PGT-A in cases with a history of recurrent implantation failure (RIF), 4.38% (n = 22) in cycles with recurrent pregnancy loss (RPL), and 1.59% (n = 8) for elective single embryo transfer (eSET). These findings indicate that while some clinicians reserve PGT-A for specific clinical indications, the majority do not apply it routinely in donor oocyte cycles, in line with current evidence-based recommendations.

PICO 8: IS THE INCLUSION OF DAY 7 BLASTOCYSTS FOR PREIMPLANTATION GENETIC TESTING COST-EFFECTIVE IN TERMS OF THE EUPLOIDY RATES REPORTED?

Recommendation

The routine inclusion of day 7 blastocysts for PGT-A in all IVF cycles is not currently recommended due to significantly lower euploidy rates and clinical success rates.

Summary of Evidence

A retrospective cohort study showed a reduction in the prevalence of euploidy by

increasing time to embryo blastulation and sustained implantation rate (SIR) of euploid day 7 SET appeared slightly lower than that of days 5 and 6 embryos.

However, routine culture through day 7 may successfully increase the pool of transferable embryos for patients who would otherwise have no usable embryos if culture is terminated on day 6. This is particularly true for older patients (>35 years), whose embryos take longer to blastulate and, therefore, are more susceptible to cycle cancellation.[14] A retrospective cohort analysis found the rate of embryo euploidy was significantly lower in day 7 blastocysts compared to day 5 or day 6 cohorts, and also there was a significant decrease in the odds of implantation, clinical pregnancy, and Live birth rate in day 7 blastocyst transfer.[15]

Research Gaps

Lack of randomized controlled trials.

Survey Results from India (Fig. 8)

- 44.75% (n = 226) respondents considered performing PGT-A at the blastocyst stage (day 5), reflecting a preference for chromosomal assessment at this developmental stage.
- 39.41% (n = 199) respondents considered performing PGT-A on embryos at both day 5 and day 6, indicating flexibility in blastocyst-stage assessment.
- 15.05% (n = 76) respondents considered performing PGT-A on embryos at day 5, 6, and 7, reflecting a broader approach to blastocyst-stage chromosomal assessment.
- 0.79% (n = 4) respondents considered performing PGT-A exclusively on day 6 embryos.

Choices	Percentage	Count
Day 5 embryos	44.75%	226
Options b & c only	39.41%	199
Options B,C & D	15.05%	76
Day 6 embryos	0.79%	4
	Total	505
	Unanswered	2

Fig. 8: Timing of PGT-A at blastocyst stage

Integration with Evidence and Key Good Practice Point

Survey results revealed variation in the day of blastocyst formation at which PGT-A was performed. The largest proportion of respondents (44.75%, n = 226) preferred performing PGT-A on day 5 embryos, consistent with evidence indicating higher euploidy and implantation rates at this stage. A substantial number (39.41%, n = 199) considered testing embryos on both day 5 and day 6, reflecting clinical flexibility while acknowledging that delayed blastulation may be associated with slightly lower implantation potential. A smaller group (15.05%, n = 76) included day 7 embryos, whereas very few (0.79%, n = 4) performed PGT-A exclusively on day 6 embryos. Although current evidence does not support routine inclusion of day 7 blastocysts for PGT-A due to their lower euploidy and live birth rates, it is important to note that their limited use primarily reflects their rarity, as only a small proportion of embryos reach the blastocyst stage by day 7.

PICO 9: IN THE SETTING OF A PATIENT REQUIRING PREIMPLANTATION GENETIC TESTING FOR MONOGENIC DISORDERS (PGT-M), IS CONCURRENT PGT-A TESTING RECOMMENDED?

Recommendation

For patients undergoing PGTM, concurrent PGTA testing is generally recommended, provided they are willing and financially able.

Summary of Evidence

A systematic review of observational studies (51 studies) reveals promising clinical outcome rates in terms of clinical pregnancy and live birth rates in patients undergoing PGTM, concurrent PGTA testing.[16]

Research Gaps

Lack of randomized controlled trials.

Survey Results from India (Fig. 9)

- Among respondents, 35.46% (n = 178) reported performing PGT-A concurrently with PGT-M often.
- 34.86% (n = 175) of respondents reported performing PGT-A concurrently with PGT-M sometimes.

- 16.53% (n = 83) of respondents reported always performing PGT-A concurrently with PGT-M.
- 13.15% (n = 66) of respondents reported rarely performing PGT-A concurrently with PGT-M.

Choices	Percentage	Count
Often	35.46%	178
Sometimes	34.86%	175
Always	16.53%	83
Rarely	13.15%	66
	Total	502
	Unanswered	5

Fig. 9: Frequency of performing PGT-A concurrently with PGT-M

Integration with Evidence and Key Good Practice Point

Among respondents, 16.53% (n = 83) reported always performing preimplantation genetic testing for aneuploidy (PGT-A) concurrently with preimplantation genetic testing for monogenic disorders (PGT-M), 35.46% (n = 178) often, 34.86% (n = 175) sometimes, and 13.15% (n = 66) rarely. This aligns with current evidence, which supports that concurrent PGT-A and PGT-M is generally recommended for patients undergoing PGT-M, provided they are willing and financially able, as it enables simultaneous detection of both monogenic disorders and chromosomal aneuploidies, potentially improving embryo selection and pregnancy outcomes.

PICO 10: FOR PREVIOUSLY UNTESTED CRYOPRESERVED EMBRYOS, DO MULTIPLE ROUNDS OF VITRIFICATION, WARMING, AND BIOPSY COMPROMISE REPRODUCTIVE OUTCOMES?

Recommendation

Multiple rounds of embryo vitrification, warming, and biopsy may have a cumulative negative impact on embryo viability and reproductive outcomes and thus are not recommended.

Summary of Evidence

A systematic review and meta-analysis of 9 retrospective studies indicates that both 'double biopsy + double vitrification' and 'single biopsy + double vitrification' were associated with reduced clinical pregnancy and live birth/ongoing pregnancy rates. .[17] A systematic review and meta-analysis of 10 retrospective studies stated that both the double biopsy and double cryopreservation (BCBC) and double cryopreservation and single biopsy (CBC) were associated with reduced live birth rates compared to the control group (single biopsy and single cryopreservation, BC).[18]

Research Gaps

Lack of high-quality RCTs.

Survey Results from India (Fig. 10)

- 97.79% (N=487) of respondents recommended limiting vitrification–warming cycles to 1–2 per embryo before biopsy.
- 1.81% (n=9) of respondents recommended up to 3–4 vitrification–warming cycles per embryo before biopsy.
- 0.40% (n = 2) of respondents reported no limit on the number of vitrification–warming cycles per embryo before biopsy.

Choices	Percentage	Count
1–2 cycles	97.79%	487
3–4 cycles	1.81%	9
No limit	0.40%	2
	Total	498
	Unanswered	9

Fig. 10: Recommendations on vitrification- warming cycles before biopsy

Integration with Evidence and Key Good Practice Point

Among respondents, 97.79% (N=487) recommended limiting vitrification–warming cycles to 1–2 per embryo before biopsy, while 1.81% (n = 9) suggested

up to 3–4 cycles, and 0.40% (n = 2) reported no limit. This aligns with current evidence indicating that multiple rounds of embryo vitrification, warming, and biopsy may have a cumulative negative impact on embryo viability and reproductive outcomes. Therefore, minimizing the number of vitrification–warming cycles is generally recommended to enhance the chances of a successful pregnancy.

PICO 11: DOES PREIMPLANTATION GENETIC TESTING (PGT) FOR MEN WITH SEVERE MALE FACTOR INFERTILITY OR SURGICALLY RETRIEVED SPERMATOZOA IMPROVE THE CHANCES OF A PREGNANCY FOLLOWED BY A LIVE-BORN BABY?

Recommendation

Routine PGT-A is not recommended solely for severe male factor infertility or surgically retrieved spermatozoa, as current evidence does not demonstrate a significant improvement in live birth rates in such cases.

Summary of Evidence

Preimplantation genetic testing for aneuploidy (PGT-A) in cases of severe male factor infertility (SMFI) shows mixed results. One study found no significant improvement in live birth rates, implantation rates, or clinical pregnancy rates when using PGT-A compared to non-PGT-A transfers in SMFI cases.[19] However, another study reported that PGT-A significantly decreased early miscarriage rates without compromising cumulative ongoing pregnancy rates in SMFI couples.[20] Rushing et al.,[21] suggested that PGT-A may improve live birth rates per transfer in male factor infertility. The effectiveness of PGT-A in SMFI remains controversial, with some studies showing potential benefits while others find no significant improvements. A multicenter randomized controlled trial is currently underway to provide more definitive evidence on the effectiveness of PGT-A compared to conventional intracytoplasmic sperm injection in couples with severe male infertility.[22]

Research Gaps

- Lack of large-scale RCTs evaluating PGT-A specifically in men with severe male factor infertility or surgically retrieved sperm.
- Uncertainty remains regarding the impact of high sperm DNA fragmentation on embryonic ploidy and the ability of PGT-A to mitigate any negative consequences.

- No standardized criteria exist for when PGT-A should be considered in male factor cases, leading to heterogeneous clinical practices.
- Limited data on the long-term health of offspring conceived with surgically retrieved sperm and PGT-A.
- The effect of sperm origin (testicular vs epididymal) on epigenetic modifications and their transmission is not well understood.

Survey Results from India (Fig. 11)

- 37% (n = 187) of respondents reported considering PGT-A in cases of sperm count less than 5 million/mL
- 27% (n = 138) of respondents considered offering PGT-A in cases of surgically retrieved spermatozoa in cases of azoospermia
- 5.36% (n = 27) of respondents considered PGT-A in cases of sperm count less than 10 million/mL
- 30% (n = 152) of respondents reported not offering PGT-A in cases of severe male factor infertility

Choices	Percentage	Count
Sperm count less than 5 million/mL	37.10%	187
None of the above	30.16%	152
Azoospermia /Testicular sperm	27.38%	138
Sperm count less than 10 million/mL	5.36%	27
	Total	504
	Unanswered	3

Fig. 11: For male factor, when do you offer PGT- A? (Total=504)

Integration with Evidence and Good Practice Point

While the practice is prevalent, clinicians should be transparent with patients that the decision to use PGT-A in SMFI is often driven by institutional protocol or clinician preference rather than conclusive evidence showing improved LB. Until definitive RCT evidence emerges, the use of PGT-A in male factor infertility must be highly **individualized**. Decisions should be co-managed with the patient,

taking into account the history of previous implantation failures/miscarriages, available embryo numbers, and the cost-benefit analysis for that specific couple.

PICO 12: DOES THE USE OF NEWER PLATFORMS FOR WHOLE GENOME AMPLIFICATION (WGA)—aCGH AND NGS—OFFER BETTER RATES OF DIAGNOSIS AND TEST ACCURACY?

Recommendation

Adopt NGS-based platforms as the preferred choice for preimplantation genetic testing (PGT-A/SR/MD), as they demonstrate superior sensitivity, specificity, and diagnostic accuracy compared to aCGH.

Summary of Evidence

Recent studies have explored the effectiveness of newer platforms for Whole Genome Amplification (WGA) in preimplantation genetic testing (PGT). Next-generation sequencing (NGS) has emerged as a powerful tool for PGT, demonstrating high accuracy in detecting chromosomal abnormalities and comparable clinical outcomes to array comparative genomic hybridization (aCGH).[23] NGS offers Superior resolution (~1 Mb or lower), can detect segmental aneuploidies, low-level mosaicism, and balanced translocations (in conjunction with parental karyotyping). NGS has high diagnostic accuracy (~>99% sensitivity/specificity), better error correction with barcoding, and depth of coverage.

Research Gaps

- Lack of uniform validation protocols across laboratories for WGA performance, leading to inter-lab variability in results.
- Limited large-scale RCTs comparing clinical outcomes (live birth rates) between aCGH and NGS platforms.
- Inadequate understanding of the biological significance of low-level mosaicism detected by NGS, and the optimal thresholds for embryo transfer decisions.
- Cost-effectiveness studies are sparse, especially in low-resource or mid-resource settings where aCGH may still be used.

Survey Results from India (Fig. 12)

- 62% (n = 313) of respondents reported using NGS as the genetic platform of choice
- 23.7% (n = 119) of respondents were unaware of the genetic platform used for PGT-A

- 10.76% (n = 54) of respondents reported using Fluorescent in Situ Hybridization (FISH) for sample analysis for PGT-A
- Only 3% (n =16) of respondents reported using a-CGH for analysis of PGT-A samples.

Choices	Percentage	Count
NGS	62.35%	313
I don't know	23.71%	119
FISH	10.76%	54
WGS (aCGH)	3.19%	16
	Total	502
	Unanswered	5

Fig. 12: Genetic testing platforms used

Integration with Evidence and Good Practice Point

The survey results indicate that the majority of Indian clinicians aligned with the recommendation, reporting the use of NGS as their platform of choice. This suggests rapid adoption of superior technology. However, two critical issues emerge from the survey:

- **Platform unawareness:** Nearly one-quarter of respondents are unaware of the genetic platform used for PGT-A. This represents a significant risk, as the clinician cannot properly counsel the patient on the test's limitations (e.g., if an older platform like FISH is still being used).
- **Outdated technology use:** Over 10% still report using Fluorescent in Situ Hybridization (FISH), a technology that is non-comprehensive and widely considered obsolete for PGT-A due to its low resolution and inability to screen all chromosomes.

It is mandatory for every clinician ordering PGT to know the specific platform (NGS, aCGH, or FISH) and the specific laboratory protocols used to ensure informed consent and appropriate interpretation of results for the patient.

PICO 13: DO THE RESULTS OF PGT NEED TO BE CONFIRMED BY PRENATAL GENETIC TESTING?

Recommendation

Prenatal genetic testing should be routinely recommended following all PGT procedures (PGT-A, PGT-M, and PGT-SR), even when the PGT result is normal.

Summary of Evidence

Preimplantation genetic testing for monogenic conditions (PGT-M) and aneuploidy (PGT-A) are valuable reproductive options for couples at risk of genetic disorders. While PGT techniques have improved over time, the risk of misdiagnosis remains, albeit low at less than 1 in 200 pregnancies.[24] Professional bodies currently recommend confirmatory prenatal diagnostic testing following PGT-M.[24] However, a recent study found that only 6.8% of pregnancies following PGT-M underwent confirmatory testing.[25] For PGT-A, research suggests it does not significantly reduce the likelihood of abnormal prenatal screening results or the need for invasive diagnostic testing.[26] Noninvasive prenatal testing (NIPT) remains a valuable screening tool for all pregnancies, including those following PGT-A, although positive results should be interpreted cautiously in this population due to altered positive predictive value.[27]

Research Gaps

- Lack of large-scale prospective studies quantifying the discordance rate between PGT and prenatal diagnostics across diverse patient populations.
- Limited data on long-term outcomes of children born after PGT without prenatal testing.
- Insufficient consensus on whether NIPT is adequate for low-risk confirmation post-PGT-A in certain patient subsets.
- Patient perspectives and compliance with prenatal testing after PGT are not well-explored, especially in low-resource settings.

Survey Results from India (Fig. 13)

- Nearly 40% (n = 199) of respondents recommended prenatal genetic testing after cases of PGT-M
- 33% (n = 166) of respondents recommended prenatal genetic testing after all cases of PGT
- Nearly 25% (n = 123) of respondents reported using prenatal genetic testing as per the demands of the patients

- Less than 1% (n =4) of respondents reported never recommending prenatal genetic testing after cases of PGT

Choices	Percentage	Count
In cases of PGT-M	39.80%	199
In all cases of PGT	33.20%	166
As per patient's demands	24.60%	123
In all cases of PGT-A	1.60%	8
I never recommend	0.80%	4
	Total	500
	Unanswered	7

Fig. 13: Do you recommend prenatal genetic testing after PGT ? (Total=500)

Integration with Evidence and Good Practice Point

The clinical consensus is clear that PGT, while highly accurate, is a screening/diagnostic tool that does not eliminate the need for prenatal confirmation. However, the survey results indicate significant variability in how and when prenatal testing is actually recommended or performed. The Recommendation is definitive: Prenatal genetic testing should be routinely recommended following all PGT procedures (PGT-A, PGT-M, and PGT-SR), even when the PGT result is normal. This is based on the low, but non-zero, risk of misdiagnosis (reported as less than 1 in 200 pregnancies).

The Summary of Evidence shows that for PGT-M (monogenic conditions), professional bodies *mandate* confirmatory testing. However, a study showed that only 40% of PGT-M pregnancies underwent this essential confirmation, highlighting a massive gap between professional guidance and patient/clinician adherence.

PICO 14: SHOULD EMBRYOS WITH LOW-LEVEL MOSAICISM (20–50% ABNORMAL CELLS) BE CHOSEN FOR TRANSFER IF NO EUPLOID EMBRYO IS AVAILABLE, COMPARED TO NOT TRANSFERRING SUCH EMBRYOS, IN TERMS OF CLINICAL PREGNANCY OUTCOMES?

Recommendation

Low-level mosaic embryos (20–50%) may be considered for transfer if no euploid embryos are available, after detailed genetic counselling about associated risks and clinical uncertainty.

Summary of Evidence

Recent studies suggest that transferring mosaic embryos with low-level mosaicism (20-50% abnormal cells) can be a viable option when no euploid embryos are available. Lee et al.,[28] found no significant differences in clinical outcomes between low-mosaic and euploid embryo transfers, with low-mosaic embryos resulting in healthy live births. Galain et al.,[29] reported similar live birth rates for mosaic and euploid embryos, although pregnancy loss rates were slightly higher for mosaic transfers. Zhang et al.,[30] observed lower live birth rates for mosaic embryos compared to euploid ones (46.6% vs. 59.1%), but still considered it a reasonable alternative. Spinella et al.,[31] demonstrated that embryos with <50% mosaicism had similar clinical outcomes to euploid embryos, while those with ≥50% mosaicism had significantly lower success rates. These findings suggest that transferring low-level mosaic embryos can lead to successful pregnancies and healthy births when euploid embryos are unavailable.

Research Gaps

- Lack of uniform thresholds and standardized bioinformatics pipelines for defining and reporting mosaicism across labs.
- Inconsistent embryo biopsy techniques and WGA protocols may affect the detection and classification of mosaicism.
- Limited long-term neurodevelopmental follow-up studies of children born from mosaic embryos.
- Unresolved biological questions around self-correction, the impact of specific chromosomes, and the predictive value of trophectoderm mosaicism for fetal development.

Survey Results from India (Fig. 14)

- 70% (n = 353) of respondents reported using Euploid embryos preferentially, and when no euploid embryo was available, low-level mosaic embryos.
- About 30% of the respondents recommended transferring strictly euploid embryos, and not utilising low-level mosaic embryos.

Choices	Percentage	Count
Options a and b	70.04%	353
Only Euploid embryos	29.37%	148
Low level mosaicism (20%-50% abnormal cells) when no euploid available	0.40%	2
No embryos transferred	0.20%	1
	Total	**504**
	Unanswered	3

Fig. 14: Which embryos do you transfer? (Total=504)

Integration with Evidence and Good Practice Point

The integration of current evidence and local practice suggests that while euploid embryos remain the ideal first choice, low-level mosaic embryos offer a reasonable and successful alternative, necessitating a strong focus on risk stratification and patient counselling.

The formal recommendation is to consider low-level mosaic embryos (20–50%) for transfer if no euploid embryos are available. This is strongly supported by the Summary of Evidence, which shows that successful pregnancies and healthy live births have been achieved using low-level mosaic embryos. The Survey Results indicate that 70% of Indian respondents align with this approach, preferentially using low-level mosaics when euploid options are exhausted. This high adoption rate reflects the utility of these embryos in maximizing the chance of pregnancy for patients with limited options.

PICO 15: FOR COUPLES UNDERGOING IVF, DOES NONINVASIVE PREIMPLANTATION GENETIC TESTING (NIPGT) USING SPENT CULTURE MEDIA OFFER THE SAME LEVEL OF ACCURACY AND CONCORDANCE AS THE STANDARD PGT WITH TROPHOECTODERM BIOPSY?

Recommendation

niPGT should not currently replace standard PGT-A in clinical decision-making, especially in cases requiring high diagnostic precision (e.g., known genetic conditions, single embryo transfer, or advanced maternal age).

Summary of Evidence

Recent studies have investigated the accuracy of noninvasive preimplantation genetic testing (niPGT) using spent culture media (SCM) compared to standard trophectoderm (TE) biopsy. Chen et al.,[32] found that niPGT using SCM had similar diagnostic efficiency to TE biopsy, with potentially higher reliability for mosaic embryos. Shitara et al.,[33] reported that niPGT may be more accurate than TE biopsy when compared to outgrowth samples. However, Avila Perez et al.,[34] concluded that truly noninvasive PGT had insufficient accuracy for clinical use. Strychalska et al.,[35] observed higher concordance between niPGT and TE biopsy results for day 6 embryos (94.5%) compared to day 5 embryos (55.7%). While these studies show promise for niPGT, there are inconsistencies in reported accuracy levels. Factors such as embryo manipulation, culture duration, and potential contamination may influence results, highlighting the need for further research to establish the reliability of niPGT for clinical application.

Research Gaps

- Lack of standardized laboratory protocols for niPGT—media type, culture duration, DNA extraction, and amplification techniques varies widely.
- Variable concordance rates depending on culture media, patient population, and embryo stage—leading to inconsistent clinical translation.
- No large-scale randomized trials comparing clinical pregnancy, implantation, and live birth outcomes of niPGT-guided transfers vs standard PGT-A.
- Long-term neonatal outcome data for embryos selected based solely on niPGT are lacking.

- The biological origin and timing of cfDNA release (TE vs ICM vs apoptotic debris) are not well understood, affecting clinical reliability.

Survey Results from India (Fig. 15)

- Nearly 38% (n = 188) of respondents felt the need for more studies on concordance rates for niPGT
- About 25% (n = 126) of respondents reported that niPGT requires more validation before routine clinical use
- Another 24% (n = 121) of respondents felt that the technique is ready for clinical use
- 13% (n = 65) of respondents reported already using niPGT in their clinical practice

Choices	Percentage	Count
We need to have more studies on concordance rates	37.60%	188
It still needs validation	25.20%	126
We are ready to use it	24.20%	121
I am already using it	13.00%	65
	Total	**500**
	Unanswered	7

Fig. 15: What is your opinion about niPGT? (Total=500)

Integration with Evidence and Good Practice Point

The integration of current evidence and local practice reveals that niPGT holds immense promise due to its noninvasive nature, but significant inconsistencies in accuracy and a lack of large-scale validation mean it cannot yet replace the established standard of care.

The formal recommendation is unambiguous: niPGT should not currently replace standard PGT-A in clinical decision-making. The Summary of Evidence

confirms this caution, noting inconsistencies and variability in reported accuracy, with some studies finding insufficient accuracy for clinical use.

Until randomized controlled trials (RCTs) confirm that niPGT-guided transfers yield equivalent clinical pregnancy and live birth rates to standard PGT-A, trophectoderm (TE) biopsy remains the only PGT method validated for making definitive embryo transfer decisions.

A critical finding from the survey results is the disconnect between the cautious recommendation and local adoption:

- 13% of respondents report already using niPGT in their clinical practice.
- 24% feel the technique is ready for clinical use.

In contrast, 37.6% respondents and nearly 25% respondents respectively feel that more studies on concordance and more validation are needed. This split indicates a strong desire among some practitioners to adopt the less-invasive technology quickly, despite the scientific uncertainties outlined in the research.

PICO 16: IN COUPLES UNDERGOING IVF FOR SUBFERTILITY, DOES INCLUSION OF PGT AS PART OF FERTILITY TREATMENT REDUCE TIME TO PREGNANCY PER IVF CYCLE, WHEN COMPARED TO EMBRYO SELECTION BASED ON MORPHOLOGY ALONE?

Recommendation

PGT-A should not be routinely offered solely to shorten the time to pregnancy without clear indications or supporting clinical factors.

Summary of Evidence

Preimplantation genetic testing for aneuploidy (PGT-A) in IVF cycles shows mixed results in reducing time to pregnancy. For women aged ≥39 years, PGT-A significantly shortens the time to live birth.[36] However, a meta-analysis found no overall difference in clinical and ongoing pregnancy rates with PGT-A compared to morphology-based selection, although spontaneous abortion rates were lower.[37] One study reported higher live birth rates from the first conception attempt with PGT-A, even in younger women.[38] Conversely, another study found that PGT-A did not decrease time to pregnancy, particularly for younger patients, and may add time and cost without significant benefit.[39] These conflicting findings suggest that the use of PGT-A should be individualized based on patient characteristics, with potential benefits more pronounced in older women.

Research Gaps

- Limited head-to-head data on TTP per cycle between PGT-A and morphology-based IVF in broader subfertility populations.
- Variability in outcome definitions (TTP per transfer vs per cycle vs cumulative TTP) across studies.
- Sparse real-world data incorporating lab processing time and delays inherent to biopsy/freeze/thaw workflows.
- Lack of uniform reporting on how long it takes from oocyte retrieval to embryo transfer in PGT-A vs non-PGT-A cycles.

Survey Results from India (Fig. 16)

- 52% (n = 260) of respondents felt that PGT-A requires more evidence for routine clinical use
- Nearly 30% (n = 148) of respondents felt that PGT-A does not make any significant difference in clinical outcomes
- 11.2% (n = 56) of respondents felt that PGT-A decreases time to pregnancy
- Only 7.2% (n = 36) of respondents felt that PGT-A increases pregnancy rate per patient

Choices	Percentage	Count
Needs more evidence	52.00%	260
Does not make any difference	29.60%	148
Decreases time to pregnancy	11.20%	56
Increases pregnancy rate per patient	7.20%	36
	Total	**500**
	Unanswered	7

Fig. 16: Does PGT-A affect time to pregnancy? (Total=500)

Integration with Evidence and Good Practice Point

The integration of clinical evidence and local survey results confirms that PGT-A should not be routinely offered solely for the purpose of shortening time to

pregnancy (TTP) in the general subfertility population, but it holds a specific, evidence-backed role for older women.

PICO 17: IN COUPLES UNDERGOING IVF-PGT, DOES THE PROCESS OF TROPHOECTODERM BIOPSY INCREASE THE RISK OF OBSTETRIC AND NEONATAL COMPLICATIONS IN FROZEN-THAWED EMBRYO TRANSFER (FET) CYCLES?

Recommendation

Trophectoderm biopsy during IVF-PGT cycles does not appear to significantly increase the risk of major obstetric or neonatal complications when compared to FET cycles without biopsy, especially when performed by experienced embryologists under optimized protocols.

Summary of Evidence

Recent studies have examined the impact of trophectoderm biopsy for preimplantation genetic testing (PGT) on obstetric and neonatal outcomes in frozen-thawed embryo transfer (FET) cycles. Three studies found an increased risk of hypertensive disorders of pregnancy associated with PGT.[40-42] However, one study reported no significant differences in obstetric outcomes between biopsied and unbiopsied embryos.[43] Ji et al.,[42] observed a higher rate of abnormal umbilical cord but a lower incidence of premature rupture of membranes in the PGT group. Regarding neonatal outcomes, most studies found no significant differences in birthweight, gestational age at delivery, or birth defects between PGT and non-PGT pregnancies.[41-43] While these findings suggest that trophectoderm biopsy may increase the risk of certain obstetric complications, its impact on neonatal outcomes appears minimal.

Research Gaps

- Limited long-term follow-up data on neurodevelopmental, cognitive, or epigenetic outcomes in children born after TE biopsy.
- Difficulty isolating biopsy effect from confounders like IVF indication, maternal age, and freezing protocol.
- Most data are retrospective, introducing bias in patient selection and confounding by indication.
- Subgroup-specific risks (e.g., twins vs singletons, male vs female fetus, fresh vs frozen PGT) need more detailed study.

- Lack of randomized controlled trials directly comparing PGT vs non-PGT FET outcomes in otherwise similar cohorts.

Survey Results from India (Fig. 17)

- 21.12% (n = 106) of respondents felt that PGT-A increases the risk of both neonatal and obstetric complications
- 71.31% (n = 368) of respondents felt that PGT-A does not increase the risk of either neonatal or obstetric complications
- 4.38% (n = 22) of respondents felt that PGT-A increases the risk of neonatal complications only
- Only 1.2% (n =6) of respondents felt that PGT-A increases the risk of obstetric complications only.

Choices	Percentage	Count
None of above	73.31%	368
Both of above	21.12%	106
Increase risk of neonatal complications	4.38%	22
Increase risk of obstetric complications	1.20%	6
	Total	502
	Unanswered	5

Fig. 17: Do you think PGT with FET increases the risk of neonatal or obstetric complications?(Total=502)

Integration with Evidence

The integration of current evidence and local survey results largely supports the conclusion that TE biopsy does not significantly increase the risk of major complications. However, practitioners must remain vigilant regarding specific, low-frequency obstetric risks and the lack of long-term safety data.

Good Practice Point

Trophectoderm biopsy during IVF-PGT cycles does not appear to significantly increase the risk of major obstetric or neonatal complications when compared

to FET cycles without biopsy, especially when performed by experienced embryologists under optimized protocols.

PICO 18: IN COUPLES UNDERGOING IVF WITH PREIMPLANTATION GENETIC TESTING (PGT), DOES PROVIDING COMPREHENSIVE COUNSELLING BEFORE STARTING THE IVF/PGT CYCLE, COMPARED TO COUNSELLING PROVIDED AFTER OOCYTE RETRIEVAL OR EMBRYO BIOPSY, LEAD TO BETTER PATIENT UNDERSTANDING, REDUCED ANXIETY, AND IMPROVED SATISFACTION WITH TREATMENT DECISIONS?

Recommendation

A strong recommendation for the patients undergoing PGT-A is to implement comprehensive counselling before the start of the IVF/PGT cycle.

Summary of Evidence

Early comprehensive counselling appears to improve patient understanding and knowledge about preimplantation genetic testing (PGT), but evidence for anxiety reduction is mixed.

A randomized controlled trial by Singh et al.,[44] found that patients receiving counselling with educational handouts and brief genetic counselling interventions demonstrated significantly higher knowledge scores both immediately post-visit (79.4–80.8%) and two weeks later (75.9–79.6%), compared to provider-only counselling (46.9–49.9%). However, the same study did not observe statistically significant differences in decisional conflict or regret, with researchers noting they were only powered to detect large differences.

Hughes et al.,[45] emphasize the importance of holistic, multidisciplinary counselling, recommending thorough evaluation and support throughout the PGT process to improve patient experiences.

Research Gaps

- High-level evidence (RCTs) is needed to definitively prove that the early timing of counselling is superior to later timing. Most current research focuses on the content of counselling, not its strategic delivery timing.
- There is no validated, standardized definition of "comprehensive counselling" for PGT across different clinics or countries.
- Variability in patient counselling protocols across clinics and limited training in the ethics of non-disclosure.

Survey Results from India (Fig. 18)

- 39.32% (n = 197) of respondents reported that they counsel the patients before the start of stimulation
- 35.53% (n = 178) clinicians counselled the patients before the biopsy procedure, once the blastocysts were available
- 19% (n = 98) of respondents counselled the patients at the start of the stimulation when PGT was planned
- 1.2% (n =6) of respondents counselled the patients at the time of PGT results
- 3.39% (n=17) of clinicians did not counsel the patients who underwent PGT at all

Choices	Percentage	Count
Before Stimulation	39.32%	197
Before biopsy, once blasto-cysts/embryos are available	35.53%	178
At the time of stimulation when PGT has been planned	19.56%	98
No	3.39%	17
At the time of PGT results	1.20%	6
Yes, If yes, when do you counsel	1.00%	5
	Total	501
	Unanswered	6

Fig 18: Do you counsel your patients before PGT? (Total = 501)

Integration with Evidence and Good Practice Point

The survey results reveal wide variability in *when* counselling is provided, with counselling occurring anywhere from the start of stimulation to after the PGT results. Given the sensitive nature of PGT, late counselling is a significant risk for decisional distress.

Clinics offering IVF with PGT should establish a mandatory good practice point to deliver comprehensive, standardized PGT counselling before the couple begins the IVF ovarian stimulation and retrieval cycle.

PICO 19: IN COUPLES UNDERGOING IVF-PGT, DOES THE ADDITION OF PGT-P (PREIMPLANTATION GENETIC TESTING FOR POLYGENIC DISEASE) BASED ON POLYGENIC RISK SCORE (PRS) OFFER A REALISTIC REDUCTION IN FUTURE DISEASE BURDEN?

Recommendation

PGT-P is still experimental and should currently not be recommended for routine clinical use in IVF programs.

Summary of Evidence

Preimplantation genetic testing for polygenic disorders (PGT-P) using polygenic risk scores (PRS) is now technically feasible but controversial. While some studies suggest potential risk reductions for certain diseases,[46] the clinical utility and ethical implications remain debated. Absolute risk reductions are estimated to be small, ranging from 0.02% to 10.1%.[47] Concerns include limited predictive power, lack of clinical validation, and potential exacerbation of health inequities.[48-49] The influence of environmental factors and rare genetic variations on disease development complicates risk assessment.[49] Ethical issues involve social inequity, consent challenges, and the need for societal debate on trait selection. While patients generally view PGT-P favourably, clinicians and professional organizations express reservations about its implementation.[47] Further research and ethical considerations are needed before widespread adoption.

Research Gaps

- Lack of prospective clinical trials demonstrating actual health outcomes in children born after PGT-P.
- No validated thresholds for PRS that reliably predict risk reduction at the embryo level.
- Minimal long-term follow-up data on children born after PGT-P.
- Lack of regulation and standardization in commercial applications.
- Insufficient exploration of ethical frameworks guiding selection based on non-medical traits.
- No data on the psychosocial impact on families who opt for PGT-P.

Survey Results from India (Fig. 19)

- 62% (n = 309) of respondents were unaware of the technique of PGT-P and PRS
- 27% (n = 134) respondents felt that embryos with lower PGT-P/PRS should be prioritized for transfer
- 10.3% (n = 51) of respondents felt that PRS is limited by its accuracy of prediction
- Only 1 respondent felt that biopsy specimens can be used for the determination of only single gene defects

Choices	Percentage	Count
I am unaware about this technique	62.17%	309
Yes, embryos with lower polygenic risk score should be prioritized for transfer	26.96%	134
PRS is limited by accuracy of prediction, and offspring arising from embryos with lower PRS can still develop the disease	10.26%	51
PRS is limited by accuracy of prediction, and offspring arising from embryos with lower PRS can still develop the disease	0.40%	2
No, biopsy specimens can be used for determination of only single gene defects	0.20%	1
	Total	**497**
	Unanswered	10

Fig. 19: Does the addition of polygenic risk score (PRS/PGT-P) offer a newer avenue of selecting embryos? (Total = 497)

Integration with Evidence and Good Practice Point

The integration of current evidence and local survey results clearly shows that PGT-P is an experimental, unvalidated technology that requires significant scientific and ethical scrutiny before it can be offered in routine clinical practice. Local awareness and confidence in the technology are currently low.

Good Practice Point

Clinicians must treat PGT-P as a research tool only. It should not be presented as a validated diagnostic service that offers a realistic, guaranteed reduction in future

disease burden. Enrolment in any PGT-P application should occur exclusively within a registered, ethically approved research protocol with robust oversight and informed consent.

KEY GOOD PRACTICE POINTS

1. In women of advanced maternal age undergoing IVF, PGT-A may be considered to enhance embryo selection and improve live birth rates, but its use should be individualized rather than routine. Comprehensive chromosome screening methods are preferred when applied. *Indian clinicians selectively offer PGT-A in women of advanced maternal age—particularly those over 35 (50.99%)or 37 years (46.83%)—to enhance the likelihood of pregnancy, reflecting an evidence-based, individualized approach rather than routine universal application.*

2. PGT-A may be considered, but not universally, with the use of PGT-A in RPL (≥2 recurrent pregnancy loss) should be individualized, taking into account maternal age, embryo availability, cause of RPL (unexplained vs known), and patient preference.
Indian clinicians appropriately prioritize PGT-A for high-risk RPL cases, such as women with advanced maternal age or poor ovarian reserve (82.3%), aligning with international recommendations to individualize treatment based on patient-specific risk factors.

3. The routine use of PGT-A is not recommended for patients with RIF.
PGT-A should not be routinely offered after a single failed IVF or in RIF, as evidence shows no significant improvement in live birth rates. Its selective use may be justified in advanced maternal age or chromosomal risk cases. The survey highlights earlier use than evidence supports, emphasizing the need to align practice with guidelines.

4. Preimplantation genetic testing for aneuploidy (PGT-A) is not recommended for routine use in good-prognosis subfertile couples, particularly in younger women with normal ovarian reserve and multiple embryos available.
Indian clinicians appropriately avoid offering PGT-A to good-prognosis subfertile patients—reflected by 89.62% not using it—consistent with international evidence showing no improvement in cumulative live birth rates in this group, thereby supporting judicious and evidence-based use of PGT-A.

5. Preimplantation genetic testing for aneuploidy (PGT-A) is not recommended for routine use to improve the utilisation of elective single embryo transfer (eSET).
   Indian clinicians appropriately reserve PGT-A prior to elective single embryo transfer (eSET) for highly selective cases, as reflected by 79.72% using it only rarely.

6. The draft recommendation would suggest that preimplantation genetic testing for aneuploidy (PGT-A) is not recommended solely on the basis of advanced paternal age.
   Indian clinicians appropriately avoid using advanced paternal age as the sole indication for PGT-A—reflected by 39.64% not considering it and only 33.27% applying it when paternal age exceeds 50 years—aligning with current evidence that paternal age has a less pronounced effect on embryo aneuploidy compared with maternal age.

7. Routine use of preimplantation genetic testing for aneuploidy (PGT-A) is not recommended in IVF cycles utilizing donor oocytes.
   Indian clinicians appropriately avoid routine PGT-A in donor oocyte cycles—reflected by 79.68% not using it—reserving it only for specific high-risk scenarios such as recurrent implantation failure (14.34%), recurrent pregnancy loss (4.38%), or elective single embryo transfer (1.59%). This practice aligns with evidence-based recommendations, recognizing the generally lower aneuploidy risk in donor eggs and supporting selective, individualized application of PGT-A.

8. The routine inclusion of day 7 blastocysts for PGT-A in all IVF cycles is not currently recommended due to significantly lower euploidy rates and clinical success rates.
   Indian clinicians appropriately perform PGT-A primarily on day 5 blastocysts (44.75%), with selective testing of day 6 embryos (39.41%) while largely avoiding day 7 blastocysts (15.05%) or exclusively day 6 embryos (0.79%). This reflects evidence-based practice, prioritizing embryos with higher euploidy and implantation potential and reserving later-developing blastocysts for selective cases only, in line with current recommendations.

9. For patients undergoing PGT-M, concurrent PGT-A testing is generally recommended, provided they are willing and financially able. *Indian clinicians appropriately offer concurrent PGT-A and PGT-M based on patient-specific considerations—reflected by 16.53% always, 35.46% often, 34.86% sometimes, and 13.15% rarely performing it—aligning with evidence that*

simultaneous testing is recommended for PGT-M patients who are willing and financially able, as it enhances embryo selection and may improve pregnancy outcomes.

10. Multiple rounds of embryo vitrification, warming, and biopsy may have a cumulative negative impact on embryo viability and reproductive outcomes and thus are not recommended.
Indian clinicians appropriately limit embryo vitrification–warming cycles before biopsy—reflected by 97.79% recommending 1–2 cycles—aligning with evidence that multiple rounds can negatively affect embryo viability and reproductive outcomes, thereby supporting practices that maximize the likelihood of a successful pregnancy.

11. Routine PGT-A is not recommended solely for severe male factor infertility (SMFI) or surgically retrieved spermatozoa, as current evidence does not demonstrate a significant improvement in live birth rates in such cases.
Though most Indian clinicians consider offering PGT-A in cases of SMFI—nearly 70%—the decision to use PGT-A in SMFI should be individualized and based on shared decision-making with patients.

12. Adopt NGS-based platforms as the preferred choice for preimplantation genetic testing (PGT-A/SR/MD), as they demonstrate superior sensitivity, specificity, and diagnostic accuracy compared to aCGH.
Most Indian fertility specialists—over 62%—appropriately use NGS as the preferred platform of choice for whole genome amplification, which is in line with the evidence that NGS-based platforms are superior to other platforms in terms of accuracy and resolution.

13. Antinatal genetic screening should be routinely recommended following all PGT procedures (PGT-A, PGT-M, and PGT-SR), even when the PGT result is normal.
The majority of Indian clinicians appropriately offer prenatal testing following PGT-M (40%) and PGT-A (33%), but owing to the sensitive nature of the accuracy of PGT results, this should be extended to all patients following PGT.

14. Low-level mosaic embryos (20–50%) may be considered for transfer if no euploid embryos are available, after detailed genetic counselling about associated risks and clinical uncertainty.
The majority of the Indian clinicians (70%) appropriately prioritized using euploid embryos for transfer, and in the absence of euploid embryos, low-level mosaic embryos, which is in line with the evidence and the recommendation.

15. niPGT should not currently replace standard PGT-A in clinical decision-making, especially in cases requiring high diagnostic precision.
A majority of Indian clinicians—nearly 63%—are appropriately cautious in offering niPGT to the patients, and feel more studies on concordance and validation for the same are needed.

16. PGT-A should not be routinely offered solely to shorten the time to pregnancy without clear indications or supporting clinical factors.
A majority of Indian clinicians—81.6%—appropriately limit the use of PGT-A with the intention of shortening the time to pregnancy, which aligns with the available evidence and recommendations.

17. Trophectoderm biopsy during IVF-PGT cycles does not appear to significantly increase the risk of major obstetric or neonatal complications when compared to FET cycles without biopsy, especially when performed by experienced embryologists under optimized protocols.
The vast majority of Indian clinicians – over 73% - rightly align with the available evidence that TE biopsy during PGT does not increase the risk of major obstetric or neonatal complications.

18. A strong recommendation for the patients undergoing PGT-A is to implement comprehensive counselling before the start of the IVF/PGT cycle.
Indian clinicians differ in the way they counsel patients before PGT-A, with about 40% counselling patients before the start of stimulation, nearly 35% counselling the patients before biopsy procedure, about 19% counselling the patients at the start of stimulation, nearly 1.2% clinicians counselling when the PGT results are available, and a surprising 3.4% clinicians not counselling the patients who underwent PGT at all.

19. PGT-P (Polygenic) is still experimental and should currently not be recommended for routine clinical use in IVF programs.
Most of the Indian clinicians—about 62%—were unaware of PGT-P and PRS as a technique, substantiating the experimental nature of the technique.

SURVEY QUESTIONNAIRE OF PREIMPLANTATION GENETIC TESTING

Basic Demographic Questions

1. Which city and state do you practice in?
   Answer: _____
2. Do you practice in:
   a. Corporate Sector
   b. Private IVF Centre
   c. Government Institutional Sector
   d. Other (Please specify): _____
3. What age group do you belong to?
   a. <30 years
   b. 30-39 years
   c. 40-49 years
   d. >50 years

Section 2: PGT Practices

1. Do you routinely offer PGT in your clinic
   a. Yes/No
      If yes, what do you offer
   b. PGT-A
   c. PGT-M
   d. PGT-SR
   e. PGT-HLA
   f. All of the above
2. Which group of patients do you offer PGT-A
   a. AMA
   b. RPL
   c. Male Factor
   d. RIF
   e. None of the above
3. For cases with AMA, do you offer PGT-A
   a. To all patients above the age of 35 years
   b. Above 37 years
   c. Donor oocyte cycles
   d. None of the above

4. For cases with RIF, after how many failures do you recommend PGT-A
   a. After one failed cycle
   b. AMA + 1 failed cycle
   c. 3 failed cycles
   d. None of the above
5. For cases with RPL, do you consider PGT-A
   a. Age > 38yrs
   b. Poor ovarian reserve
   c. Both AMA and poor ovarian reserve
   d. All ages
6. For male factors, when do you offer PGT-A
   a. Sperm count less than 10 million/ml
   b. Sperm count less than 5 million/ml
   c. Azoospermia /Testicular sperm
   d. None of the above
7. Do you consider PGT-A concurrently with PGT-M
   a. Always
   b. Often
   c. Sometimes
   d. Rarely
8. Do you offer PGT-A in good prognosis patients with subfertility
   a. Yes/No
   If yes, do you offer PGT-A
   a. Age < 35yrs
   b. Tubal factor/ male factor
   c. No prior IVF treatment
   d. Reduce time to pregnancy
9. Do you consider PGT-A prior to eSET?
   a. Always
   b. Often
   c. Sometimes
   d. Rarely
10. Do you offer PGT on
   a. Day 3 embryos
   b. Day 5 embryos
   c. Day 6 embryos
   d. Day 7 embryos
   e. NiPGT

11. Which genetic testing platform do you use?
    a. NGS
    b. WGS
    c. FISH
    d. I don't know
12. Which embryos do you transfer
    a. Only Euploid embryos
    b. Low level mosaicism (20%-50% abnormal cells) when no euploid available
    c. High level mosaicism (> 50%)when no euploid available
    d. No embryos transferred
13. Do you recommend pre-natal genetic testing after PGT ?
    a. In all cases of PGT
    b. In cases of PGT-M
    c. In all cases of PGT-A
    d. As per patient's demands
    e. I never recommend
14. What is your opinion about niPGT?
    a. I am already using it
    b. We are ready to use it
    c. It still needs validation
    d. We need to have more studies on concordance rates
15. Do you think PGT-A
    a. Increases pregnancy rate per patients
    b. Decreases time to pregnancy
    c. Does not make any difference
    d. Need more evidence
16. Do you think doing PGT with FET will
    a. Increase risk of obstetric complications
    b. Increase risk of neonatal complications
    c. Both of above
    d. None of above
17. Do you counsel your patients before PGT
    a. Yes/ No
    If yes, when do you counsel
    a. At the time of stimulation when PGT has been planned
    b. Before biopsy, once blastocysts/embryos are available
    c. At the time of PGT results
    d. Before Stimulation

18. What is the maximum number of vitrification-warming cycles you would recommend for an embryo before biopsy?
    a. 1-2 cycles
    b. 3-4 cycles
    c. More than 4 cycles
    d. No limit
19. Does the addition of polygenic risk score (PRS/PGT-P) offer a newer avenue of selecting embryos for transfer post biopsy?
    a. Yes, embryos with lower polygenic risk score should be prioritized for transfer
    b. No, biopsy specimens can be used for determination of only single gene defects
    c. PRS is limited by accuracy of prediction, and offspring arising from embryos with lower PRS can still develop the disease
    d. I am unaware about this technique
20. How many embryos do you send for PGT-A?
    a. 1
    b. 2
    c. 3
    d. > 4
21. In advanced paternal age, above which age you consider PGT-A ?
    a. > 40 yrs
    b. > 45 yrs
    c. > 50yrs
    d. None of the above
22. In donor egg cycles , when do you consider PGT-A?
    a. SET
    b. RPL
    c. RIF
    d. None of the above

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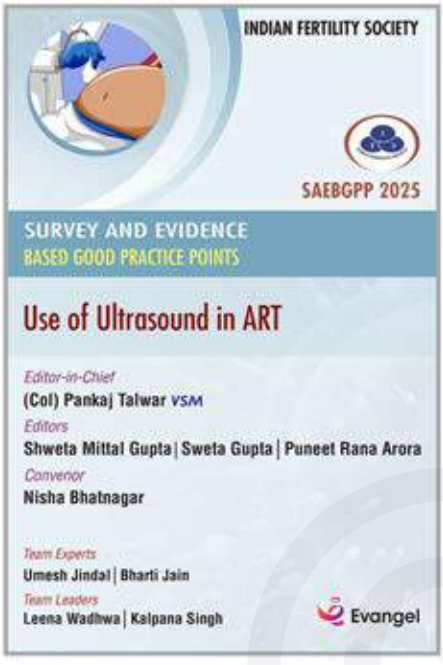
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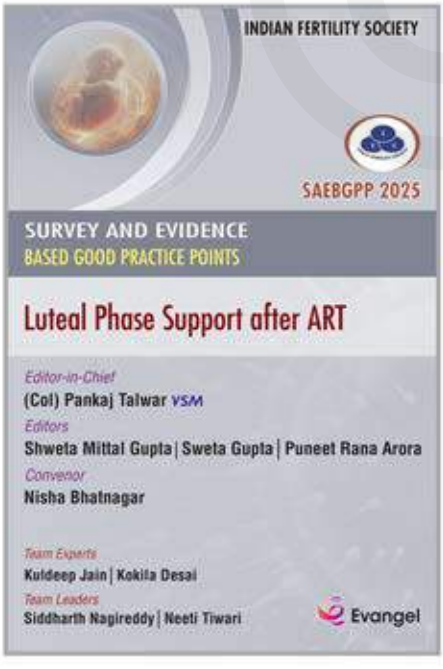
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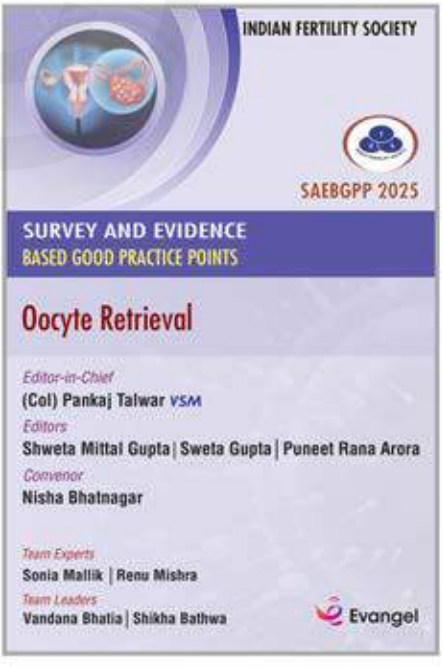
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Prof (Col) Pankaj Talwar *VSM*, is a renowned Fertility Specialist and Director, Talwar Fertility and Men's Clinic, Gurugram, Haryana, India. Recipient of the Vishisht Seva Medal from the President of India, he has performed over 17,000 IVF cycles with a success rate exceeding 60%. A PhD in Embryology and pioneer of ovarian cortex freezing in India, he has established 29 ART units globally and trained over 2,500 gynecologists across 34 countries.

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