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Comparative Evaluation of Indigenous and Commercial ICSI Culture Media: A Pre-Clinical Study

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Abstract

Background: Optimizing embryo culture conditions is essential for successful Intracytoplasmic sperm injection (ICSI). In India, several commercial culture media—such as Vitrolife, Vitromed, Cook Medical, Origio, and Sage—are widely used. However, their high costs and dependence on international supply chains limit accessibility in resource-constrained settings. The development of indigenous embryo culture media offers a promising and cost-effective alternative; however, robust comparative evidence is required to establish their efficacy and safety. Our study is the first in India to provide systematic pre-clinical validation of a locally formulated ICSI culture media under standardized laboratory conditions. **Objective:** To systematically compare embryological outcomes between a novel indigenous IVF culture media and the commercially available culture media in an Indian population undergoing intracytoplasmic sperm injection (ICSI) cycles. **Methods:** This prospective, randomized comparative study was conducted at Medical Health and Research Institute, Hyderabad, India from April 2024 to September 2025. A total of 72 women (aged 25 - 37 years) with primary or secondary infertility were enrolled. Participants were matched for baseline characteristics and randomized to receive either the indigenous or commercially available culture media. All underwent standardized ovarian stimulation, oocyte retrieval, and fertilization (ICSI). Embryos were cultured to the blastocyst stage in their assigned media. Laboratory outcomes included fertilization (2PN), cleavage,

good-quality embryos (day 3), blastocyst formation, and cryopreservation eligibility. Clinical outcomes assessed were implantation, clinical pregnancy, ongoing pregnancy, miscarriage, and live birth rates. Cumulative outcomes from both fresh and frozen transfers were also analyzed. Statistical significance was set at $p < 0.05$. **Results:** Baseline characteristics, stimulation parameters, and oocyte yields were comparable between groups. Fertilization, cleavage, and blastocyst formation rates were comparable with commercially available culture media (92%, 93%, 58%) compared to the indigenous media (89%, 91%, 52%), though not statistically significant. Rates of high-quality embryos and cryopreserved blastocysts were similar. Clinical outcomes—including pregnancy commercially available culture media 48% vs. indigenous (45%), ongoing pregnancy (44% vs. 41%), and live birth rates (40% vs. 38%)—were also comparable. Miscarriage and multiple pregnancy rates showed no significant differences between the groups. **Conclusion:** The indigenous embryo culture media supported fertilization, embryo development, and clinical pregnancy outcomes at levels equivalent to commercially available culture media. These results suggest that indigenously developed media represent a clinically viable, accessible, and cost-effective alternative to proprietary products for IVF laboratories in resource-limited environments. This has substantial implications for expanding equitable ART access in India and similar settings, without compromising reproductive success.

Keywords

In Vitro Fertilization, IVF Culture Media, Indigenous Embryo Culture Media, Commercially Available Culture Media, Embryo Development, Fertilization Rate, Blastocyst Formation, Embryo Quality, Assisted Reproductive Technology

1. Introduction

In vitro fertilization (IVF) marks a significant change in assisted reproductive technology (ART), enabling millions of infertile couples around the world to conceive [1]. A key factor in the success of intracytoplasmic sperm injection (ICSI) is the culture media used for embryo development. It provides the necessary biochemical and physiological environment to support early embryo growth outside the body [2]. Since the early days of IVF, when simple salt-based media supported cleavage-stage embryos, progress has resulted in more complex and stage-specific formulations. These new media are enriched with energy sources, amino acids, vitamins, growth factors, and antioxidants, alldesigned to mimic the changing conditions of the female reproductive system [3]. Such improvements have led to better fertilization rates, faster cleavage, successful blastocyst formation, and higher implantation outcomes [4].

Research studies have demonstrated that when culture media are carefully created and undergo thorough quality checks, both commercial and locally

made products can yield comparable embryological development and live birth rates [5]. Despite efforts to standardize practices worldwide, there is still debate regarding whether proprietary media are truly better than locally made options, especially in low- and middle-income countries. Current research studies consistently show that as long as key physicochemical factors are well maintained, the brand of the manufacturer has little impact on clinical and embryological results.

India's IVF market is one of the fastest-growing in the world and offers a variety of embryo culture media. Several commercial products are frequently used, including Vitrolife (Sweden), Vitromed (Germany), Cook Medical (Australia), Origio (Denmark), Sage (CooperSurgical, USA), and Global Total (LifeGlobal, USA). These well-known formulations are valued for their reliability and consistent composition. However, their high prices, dependence on imported materials, and issues with cold-chain supply make them difficult for smaller or resource-limited IVF centers to obtain. As a result, many Indian couples find IVF treatment too expensive, even with the country's expanding ART infrastructure and rising infertility rates along with increased demand for ART [6]. In response, Indian biotechnology and ART research teams have developed local embryo culture media as budget-friendly alternatives. These formulations aim to match the effectiveness of commercial brands while improving affordability, availability, and supply reliability [7]. Early evaluations indicate that these local media achieve fertilization, cleavage, and blastocyst formation rates comparable to those of commercial products [8] [9]. Their simpler designs and ability to adapt to different laboratory settings make them especially suitable for IVF programs in Tier 2 and Tier 3 cities, where infrastructure or cold-chain capacity may be limited.

Studies conducted in India have validated that local IVF media can maintain similar rates of fertilization, cleavage, blastocyst formation, and clinical pregnancy. Such observations have overcome initial concerns about their safety and efficacy [10]. Unlike commercially available culture media, which sometimes contain stage-specific additives and complex mixes of nutrients to support evolving embryo needs, local formulations are simple, reproducible, and cost-effective without harming embryo viability [9]. This strategy fits well with IVF clinics in Tier 2 and 3 cities and rural areas, where state-of-the-art infrastructure or cold-chain logistics may not be feasible.

Beyond their clinical and financial advantages, Indigenous IVF media support national objectives for self-reliance in healthcare technology and promote local innovations in ART. Manufacturing local media helps decentralize fertility services, increasing access across different regions and empowering local clinics. Crucially, this development does not come at the cost of clinical outcomes, thereby allowing the success of ART for a more diverse range of socio-demographic groups.

On the other hand, commercial media companies continue to invest in research to add antioxidants, metabolic effectors such as pyruvate and lactate, and growth factors to improve embryo culture conditions. This ongoing push for sophistication

aims for slight enhancements in embryo quality and pre-implantation success. However, it raises issues around cost-effectiveness and accessibility in lower-resourced environments. Moreover, research often shows little significant difference in live birth rates or neonatal results when comparing different commercial media, leading to questions about the necessity of high-priced options.

Overall, there is growing evidence showing that culture media, whether indigenous or commercial, must maintain controlled pH, osmolality, energy supply, and antioxidant capacity to protect embryonic development [11]. The main challenge is to balance cost, accessibility, and clinical effectiveness, especially in populous countries like India that are experiencing rising infertility rates. Indigenous IVF culture media also aim to reduce costs and support India's national strategies for self-reliance in biomedical technology (Atmanirbhar Bharat). These media encourage local innovation and decentralization of fertility care. By reducing reliance on imported materials, these efforts improve the sustainability and accessibility of ART services while achieving similar embryological and clinical results. This study seeks to systematically compare the embryological results from a new local culture media made in India with those from a leading commercial media (commercially available culture media). We will assess fertilization success, embryo quality, blastocyst formation, and clinical outcomes. The findings are meant to inform doctors, embryologists, and policymakers about the feasibility of using local media in standard IVF practice. This will promote sustainable and inclusive ART services across India.

2. Materials and Methodology

2.1. Study Design and Patient Selection

This is a prospective, comparative study conducted at a Medical Health and Research Institute, Hyderabad, India, from April 2024 to September 2025, enrolling women undergoing intracytoplasmic sperm injection (ICSI) cycles over stated study period. The protocol was approved by the Institutional Ethics Review Board. Inclusion criteria encompassed women aged 25 - 37 years with primary or secondary infertility who were candidates for ovarian stimulation under a standardized antagonist protocol. Patients were randomly allocated into two groups: those receiving indigenous culture media and those assigned to commercially available culture media. Key exclusion criteria were diminished ovarian reserve, severe endometriosis, or known metabolic or genetic disorders affecting reproductive outcomes.

2.2. Patient Selection

The study recruited a total of 72 women undergoing ICSI treatment who were enrolled and randomly distributed into two groups of equal size (n = 36 each). One group utilized an indigenous IVF culture media developed locally, while the second group employed commercially available culture media, a commercial IVF culture media. Participants in both groups were matched for age (range 25 - 37

years), infertility etiology—including polycystic ovary syndrome (PCOS), tubal factor infertility, male factor infertility, and unexplained infertility—along with baseline ovarian reserve and stimulation parameters. This ensured homogeneity across groups in key prognostic variables.

Participants were randomly allocated to either the indigenous culture media group or the commercially available culture media group using a computer-generated randomization sequence. Block randomization was employed to ensure balanced allocation and minimize selection bias. Allocation concealment was maintained until the initiation of laboratory procedures to preserve the integrity of the randomization process.

To minimize observer bias, embryologists grading embryos and clinicians assessing clinical outcomes were blinded to media allocation. Culture dishes were coded by independent laboratory personnel not involved in assessment, ensuring objective evaluation.

2.3. Controlled Ovarian Stimulation and Oocyte Retrieval

All the subjects underwent controlled ovarian hyperstimulation using a standardized antagonist protocol. The gonadotropin dose and stimulation duration were tailored per individual ovarian response, assessed by serial ultrasound and serum estradiol levels. When at least three follicles reached ≥18 mm in diameter, final oocyte maturation was induced with human chorionic gonadotropin (hCG) once the criteria for follicular development were met. Oocyte retrieval was performed transvaginally 34 - 36 hours post-trigger under ultrasound guidance.

2.4. Fertilization Procedure and Embryo Culture

The indigenous culture medium has been characterized by defined pH range, controlled osmolality, balanced energy substrates (pyruvate and lactate), essential and non-essential amino acids, antioxidant components, and protein supplementation. Quality assurance included sterility testing, endotoxin assessment, and batch-to-batch validation.

Retrieved oocytes were denuded and assessed for maturity before insemination (presence of metaphase II spindle). Fertilization was conducted via intracytoplasmic sperm injection (ICSI) according to semen quality. Post-fertilization, zygotes were cultured exclusively in their assigned media—indigenous or commercially available culture media—within a controlled environment (37˚C, 5% CO_2, 5% O_2, and adequate humidity). Embryo development was monitored daily with assessments for pronuclei formation (2PN and abnormal forms), cleavage rates, and morphological grading at cleavage (Day 2 - 3) and blastocyst stages (Day 5 - 6).

2.5. Embryo Transfer and Outcome Assessment

Embryos meeting quality criteria were selected for fresh transfer or cryopreservation according to clinic protocols. Clinical pregnancy was confirmed by the presence

of a gestational sac on transvaginal ultrasound 6 weeks post-transfer. Secondary outcomes included implantation rates, ongoing pregnancy beyond 12 weeks, miscarriage, and live birth rates.

2.6. Outcome Measures

The primary outcomes included normal fertilization rate (2PN), cleavage rate, the proportion of good-quality embryos on day 3, blastocyst formation rate, and clinical pregnancy rate per embryo transfer. The secondary outcomes were ongoing pregnancy beyond 12 weeks, miscarriage rate, and live birth rate. Baseline demographic and clinical characteristics were matched between groups to minimize confounding.

2.7. Data Collection and Statistical Analysis

This study was designed as a prospective comparative pre-clinical evaluation and not as a formal non-inferiority or equivalence trial. No predefined non-inferiority margins were established. Although statistical comparisons were performed with significance set at $p < 0.05$, the sample size may be underpowered to detect small but clinically meaningful differences.

Demographic, clinical, embryological, and outcome data were prospectively collected. Statistical analyses were performed using appropriate parametric or non-parametric tests (e.g., Student's t-test, chi-square test) to compare groups, with p-values < 0.05 considered statistically significant. Data were managed to ensure the masking of embryologists and clinicians to culture media allocation during scoring and clinical assessments.

3. Results

The baseline characteristics of patients in both the indigenous and commercially available culture media groups were closely matched, ensuring robust comparability for subsequent outcome analysis. The average female age and BMI values did not differ significantly between groups, with mean ages of 28.4 ± 2.3 and 28.6 ± 2.1 years, and BMIs of 23.5 ± 3.1 and 23.8 ± 3.2 kg/m^2, respectively (all $p > 0.05$). Duration of infertility was also comparable between the groups, with a mean duration of approximately 3.5 - 3.7 years. The distribution of primary and secondary infertility was almost identical, as were the underlying infertility etiologies: PCOS, tubal, male, and unexplained factors—all demonstrating balanced representation across study arms. This homogeneity of baseline characteristics confirms the effectiveness of randomization and minimizes the risk of confounding in interpreting reproductive outcomes (Table 1).

The ovarian stimulation and oocyte retrieval parameters between the indigenous and commercially available culture media groups showed no statistically significant differences. The average total gonadotropin dose administered was comparable (2100 ± 480 IU vs. 2050 ± 510 IU, $p = 0.67$), as was the duration of stimulation (10.2 ± 1.9 days vs. 10.4 ± 2.1 days, $p = 0.72$). Both groups yielded a similar mean

number of retrieved oocytes (4.6 ± 1.2 vs. 4.8 ± 1.3, p = 0.64), with comparable proportions of mature (metaphase II) oocytes (82% vs. 84%, p = 0.61). The number of oocytes used per cycle was consistent (3 - 4) in both groups. These findings indicate that ovarian responsiveness and oocyte yield were equivalent under both culture media conditions, reflecting similar stimulation efficacy and retrieval outcomes. This equivalence is consistent with reports comparing stimulation protocols and supports the indigenous media's adequacy for ovarian stimulation cycles in ICSI (Table 2).

Table 1. Baseline patient characteristics of indigenous media and commercially available culture media.

Parameter	Indigenous Media (n = 36)	Commercially available culture media (n = 36)	p-value
Mean Female Age (years)	28.4 ± 2.3	28.6 ± 2.1	0.74
BMI (kg/m^2)	23.5 ± 3.1	23.8 ± 3.2	0.65
Duration of infertility (years)	3.5 ± 1.8	3.7 ± 2.0	0.58
Primary Infertility (%)	61	58	0.82
Secondary Infertility (%)	39	42	0.79
Etiology of Infertility			
PCOS	14	14	—
Tubal Factor	9	9	—
Male Factor	5	5	—
Unexplained	4	4	—

Table 2. Ovarian stimulation and oocyte retrieval outcomes in indigenous media and commercially available culture media.

Parameter	Indigenous Media	Commercially available culture media	p-value
Average Gonadotropin Dose (IU)	2100 ± 480	2050 ± 510	0.67
Duration of stimulation(days)	10.2 ± 1.9	10.4 ± 2.1	0.72
Mean Oocytes Retrieved	4.6 ± 1.2	4.8 ± 1.3	0.64
Mature Oocytes (MII) (%)	82	84	0.61
Oocytes Used per Cycle	3 - 4	3 - 4	—

The fertilization and early embryo development outcomes did not differ significantly between the indigenous and commercially available culture media groups. Normal fertilization, defined by the presence of two pronuclei (2PN), was observed in 89% and 92% of oocytes respectively, nearing statistical significance (p = 0.05). Abnormal fertilization rates (1PN/3PN) were low and comparable (4% vs. 3%, p = 0.48), consistent with standard clinical expectations. Pronuclei development rates were 72% for the indigenous media and 78% for commercially available culture media, also approaching significance (p = 0.05). Cleavage rates

on day 2 to 3 post-fertilization were similarly high and comparable (91% vs. 93%, p = 0.41), along with the proportion of good-quality embryos on day 3 (68% vs. 70%, p = 0.57). These results demonstrate that both media equally support normal fertilization events and early embryonic cleavage without significant differences in embryo quality at this stage (Table 3).

Table 3. Fertilization and early embryo development outcomes.

Outcome	Indigenous Media (%)	Commercially available Culture Media (%)	p-value
Normal fertilization rate (2PN)	89	92	0.05
Abnormal Fertilization (1PN/3PN)	4	3	0.48
Pronuclei Development	72	78	0.05
Cleavage Rate (Day 2 - 3)	91	93	0.41
Good Quality Embryos (Day 3)	68	70	0.57

Blastocyst development outcomes showed no statistically significant differences between the indigenous and commercially available culture media. The blastocyst formation rate was 52% in the indigenous media group compared to 58% in the commercially available culture media group, with the difference approaching significance (p = enrolling women undergoing intracytoplasmic sperm injection (ICSI) cycles over stated period). Rates of high-quality blastocysts (graded 3BB or above) were comparable at 34% and 38%, respectively (p = 0.47). Similarly, the proportion of fully expanded blastocysts was 29% versus 32% (p = 0.63), and the percentages of cryopreserved blastocysts were 18% and 21% (p = 0.52) for indigenous and commercially available culture media, respectively. These data indicate that both culture media provide comparable support for advanced embryonic development to the blastocyst stage, consistent with the performance expected in standard ICSI culture protocols (Table 4).

Table 4. Comparison of blastocyst development outcomes in indigenous media and commercially available culture media.

Outcome	Indigenous Media (%)	Commercially available culture Media (%)	p-value
Blastocyst Formation Rate	52	58	0.05
High-quality Blastocysts (≥3 BB)	34	38	0.47
Full/Expanded Blastocyst Rate	29	32	0.63
Cryopreserved Blastocysts	18	21	0.52

Clinical outcomes between the indigenous and commercially available culture media groups were comparable without statistically significant differences. The implantation rate per embryo transferred was 32% for the indigenous group and

34% for commercially available culture media (p = 0.66). The clinical pregnancy rates were 45% and 48% respectively, with p = 0.05 indicating borderline significance. Ongoing pregnancy rates beyond 12 weeks of gestation were 41% versus 44% (p = 0.59), while miscarriage rates were low and similar at 9% and 8% (p = 0.82). The estimated live birth rates were also analogous at 38% and 40% (p = 0.74). These findings collectively demonstrate that the indigenous culture media supports successful implantation, clinical pregnancy, and live birth outcomes equivalent to the commercially available media, reflecting similar clinical efficacy in ICSI treatment protocols (Table 5).

Table 5. Clinical outcomes of indigenous media and commercially available culture media.

Clinical Outcome	Indigenous Media (%)	Commercially available culture media (%)	p-value
Implantation Rate (per embryo)	32	34	0.66
Clinical Pregnancy Rate	45	48	0.05
Ongoing Pregnancy (>12 weeks)	41	44	0.59
Miscarriage Rate	9	8	0.82
Live Birth Rate (estimated)	38	40	0.74

The cumulative reproductive outcomes encompassing fresh and frozen embryo transfers were comparable between the indigenous and commercially available culture media groups. A total of 29 transfers were performed in the indigenous group and 31 in the commercially available culture media group. The cumulative pregnancy rate was 51% for indigenous media versus 54% for commercially available culture media (p = 0.63), while cumulative live birth rates were 44% and 47%, respectively (p = 0.58). The incidence of multiple pregnancies was low and similar in both groups, recorded at 6% and 7% (p = 0.88). These findings demonstrate equivalent long-term reproductive success following use of either culture media, affirming the indigenous media as a viable option in ICSI protocols inclusive of fresh and cryopreserved embryo transfers (Table 6).

Table 6. Cumulative outcomes (Fresh + Frozen Transfers) of indigenous media and commercially available culture media.

Outcome	Indigenous Media (%)	Commercially Available culture media (%)	p-value
Total Transfers Performed	29	31	—
Cumulative Pregnancy Rate	51	54	0.63
Cumulative Live Birth Rate	44	47	0.58
Multiple Pregnancy Rate	6	7	0.88

The combined embryological and clinical outcomes demonstrated that the fertilization rate in the indigenous media group was 89%, compared to 92% in the

commercially available culture media group, with the observed difference approaching statistical significance (p = 0.05). The pronuclei development and early embryonic development rates were both 72% versus 78% in the indigenous and commercially available culture media groups, respectively, also nearing significance (p = 0.05). Blastocyst formation rates were 52% compared to 58%, and conception rates were 45% versus 48%, similarly showing p = 0.05 values. These aggregated results indicate comparable performance of the indigenous and commercially available culture media throughout critical stages of embryological development and clinical conception, supporting the viability of the indigenous media as an effective alternative for embryo culture in ICSI procedures (Table 7).

Table 7. Embryological and clinical outcomes in Indigenous media and commercially available culture media.

Outcome	Indigenous Media	Commercially available culture media	p-value
Fertilization Rate	89%	92%	
Pronuclei Development	72%	78%	
Early Embryonic Development	72%	78%	0.05
Blastocyst Formation	52%	58%	
Conception Rate	45%	48%	

The outcomes were analyzed by transfer type, both fresh and frozen embryo transfer cycles demonstrated comparable reproductive performance between the indigenous and commercially available culture media.

In fresh embryo transfer (ET) cycles**,** clinical pregnancies occurred in 8 of 18 (44.4%) cases in the indigenous media group and 9 of 19 (47.4%) in the commercially available culture media group (p = 0.67). Corresponding live birth rates were 33.3% and 36.8%, respectively, with one multiple gestation recorded in each cohort.

Among frozen embryo transfer (FET) cycles**,** pregnancy was achieved in 5 of 11 (45.5%) and 6 of 12 (50.0%) transfers using the indigenous and commercially available culture media, respectively (p = 0.61). Live birth rates remained statistically indistinguishable—36.4% versus 41.7% (p = 0.66)—and no significant variation in the incidence of multiple pregnancies was observed.

Cumulative outcomes, integrating both fresh and frozen transfers, further demonstrated no statistically significant differences between the two formulations. The cumulative clinical pregnancy rate was 44.8% for the indigenous media and 48.4% for commercially available culture media (p = 0.63), while cumulative live birth rates were 37.9% and 41.9% (p = 0.58), respectively. The overall multiple pregnancy rate remained below 7% in both groups.

These findings collectively indicate that the indigenous embryo culture media perform comparably to the established commercially available culture media formulation in supporting embryo implantation, clinical pregnancy, and live birth outcomes across both fresh and cryopreserved transfer cycles (Table 8).

Table 8. Comparative outcomes for fresh, frozen, and cumulative embryo transfers between indigenous and commercially available culture media.

Outcome	Indigenous Media (n = 36)	Commercially available culture media (n = 36)	p-value
Total Transfers Performed	29 (100%)	31 (100%)	—
Fresh Embryo Transfers (ET)			
Number of Fresh Transfers	18	19	—
Clinical Pregnancy	8/18 (44%)	9/19 (47%)	0.67
Live Births	6/18 (33%)	7/19 (37%)	0.72
Multiple Pregnancy	1/18 (6%)	1/19 (5%)	0.84
Frozen Embryo Transfers (FET)			
Number of Frozen Transfers	11	12	—
Clinical Pregnancy	5/11 (45%)	6/12 (50%)	0.61
Live Births	4/11 (36%)	5/12 (42%)	0.66
Multiple Pregnancy	0/11 (0%)	1/12 (8%)	0.90
Cumulative Outcomes (Fresh + Frozen)			
Total Pregnancies	13/29 (45%)	15/31 (48%)	0.63
Cumulative Live Births	11/29 (38%)	13/31 (42%)	0.58
Overall Multiple Pregnancies	2/29 (7%)	2/31 (6%)	0.88

The comparative analysis of key ICSI outcomes between indigenous and commercially available culture media is depicted in the accompanying bar graph. The indigenous media group demonstrated a fertilization rate of approximately 88%, which was marginally lower than the 92% observed in the commercially available media group. Pronuclei development and early embryonic development rates followed a similar trend, with the indigenous media exhibiting rates around 72%, compared to approximately 78% for the commercially available culture media. Blastocyst formation rates were 52% and 58% for indigenous and commercially available culture media, respectively, while conception rates were 45% and 48%.

Overall, although the commercially available culture media consistently displayed comparable success rate percentages across all measured parameters, these differences were not statistically significant. This indicates that the indigenous media supports embryological milestones and clinical conception at levels comparable to the commercially available culture media. Such findings endorse the indigenous media as a credible alternative for ICSI culture, potentially offering cost-effective and locally accessible options without compromising reproductive outcomes (Figure 1).

The pie charts illustrate the conception rates achieved with indigenous and commercially available culture media during ICSI treatment cycles. For the indigenous media, the conception rate was 45%, indicating successful pregnancy establishment in nearly half of the cases, with the remaining 55% resulting in no

conception. In comparison, the commercially available culture media group demonstrated a comparable conception rate of 48%, with 52% of cycles not resulting in conception.

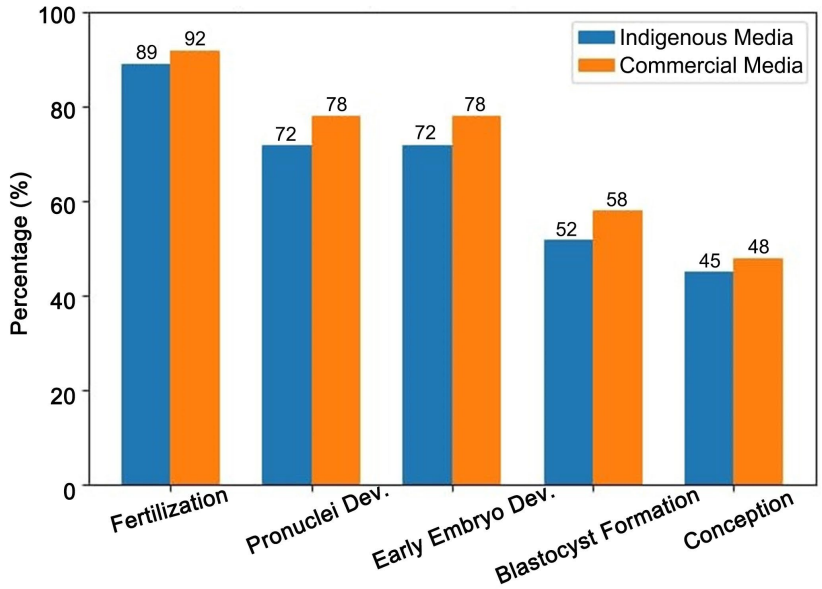

Figure 1. Barchart showing the comparison of key ICSI outcomes between indigenous and commercially available media.

The close similarity in conception rates between the two groups suggests that the indigenous culture media is practically equivalent to the commercially available culture media in facilitating successful conception in ICSI cycles. This visual comparison reinforces findings from other outcome measures, supporting the indigenous media as a cost-effective alternative for ICSI embryo culture without compromising clinical efficacy (**Figure 2**).

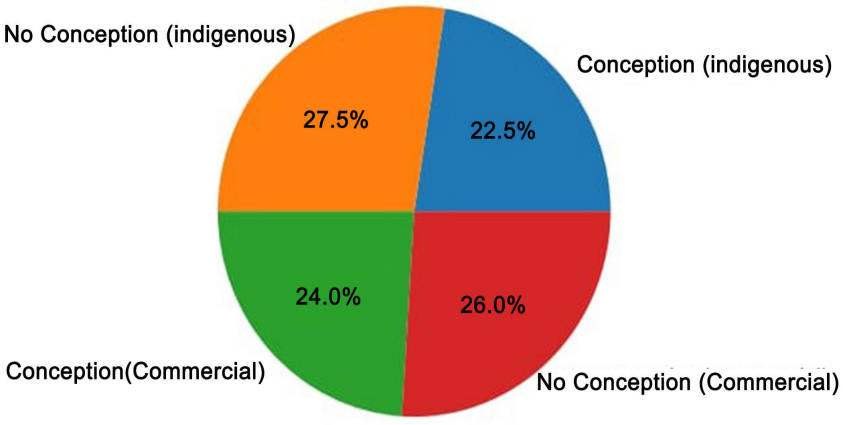

Figure 2. Pie chart comparison of conception rates between indigenous and commercially available culture media in ICSI cycles.

The pie charts compare blastocyst formation rates in two different culture media: Indigenous Media and commercially available culture media.

In the Indigenous Media-Blastocyst Formation, 52% of samples successfully formed blastocysts, whereas 48% did not form blastocysts. This indicates a nearly equal proportion of blastocyst development in the indigenous media. Commercially available media—Blastocyst Formation shows a higher blastocyst formation rate of 58%, with 42% of samples failing to form blastocysts. This suggests that the commercially available media may support blastocyst formation more effectively than the indigenous media.

Overall, these data suggest that the choice of culture media can influence the efficiency of blastocyst formation, with commercially available culture media potentially providing a more favorable environment for embryonic development at the blastocyst stage. Further investigation into the specific components and conditions of these media would be required to elucidate the underlying mechanisms driving these differences (Figure 3).

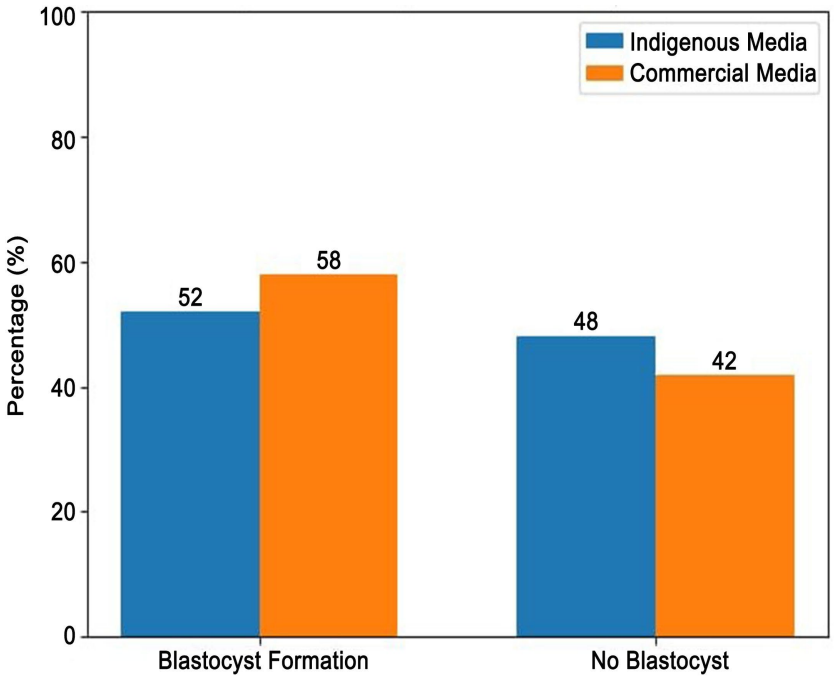

Figure 3. Comparison of blastocyst formation between indigenous and commercially available culture media in ICSI cycles.

The bar chart demonstrates comparable clinical outcomes between indigenous and commercially available culture media, with no statistically significant differences observed across implantation, clinical pregnancy, ongoing pregnancy, miscarriage, or live birth rates. These findings suggest that commercially available culture media may offer a more supportive environment for embryo development and subsequent pregnancy success than the Indigenous media (Figure 4).

4. Discussion

The present study demonstrates that indigenous and commercially available culture media perform comparably across key embryological and clinical metrics in ICSI treatment, including fertilization, early embryo development, blastocyst formation, and pregnancy outcomes. It is important to emphasize that this study was not powered as a non-inferiority or equivalence trial. Although no statistically significant differences were observed, the modest sample size limits definitive conclusions regarding clinical equivalence. Larger, adequately powered multicenter trials within a predefined non-inferiority framework are required.

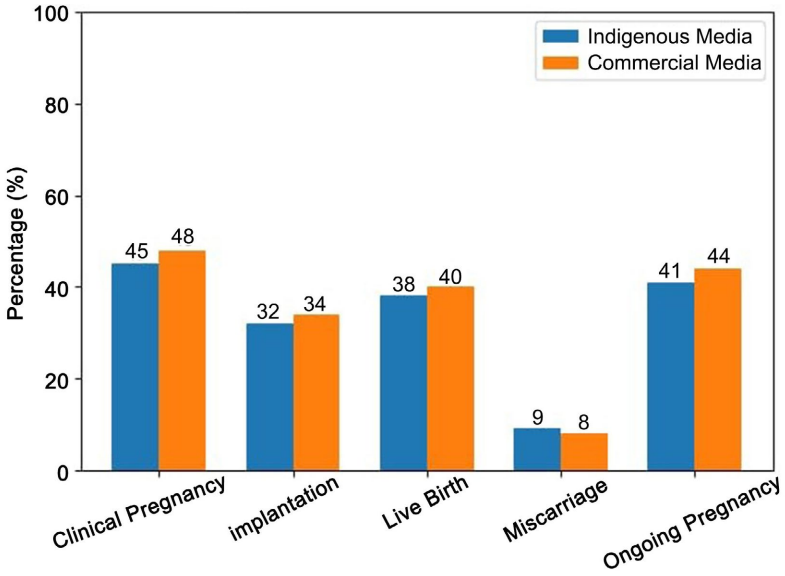

Figure 4. Barchart showing the comparison of clinical outcomes between Indigenous and commercially available culture media.

These observations are consistent with the broader literature, which repeatedly shows that differences among various commercial and non-commercial embryo culture media seldom result in clinically meaningful divergence in ICSI success rates. Filali *et al.* 2008 [12] compared TCM-199 and Medicult media in the context of *in vitro* maturation for patients with polycystic ovary syndrome and found no significant differences in oocyte maturation, fertilization, early embryo development, or pregnancy rates, supporting the conclusion that advanced commercial formulations do not necessarily provide superior results over simpler or locally prepared alternatives. Similarly, studies comparing single-step and sequential embryo culture media in clinical practice found no statistical difference in fertilization, implantation, clinical pregnancy, or miscarriage rates, although a slight increase in the number of cryopreservable embryos was sometimes observed with single media protocols [13].

A systematic review by Mantikou *et al.*, 2013 [14] further underscores the lack of clear evidence favoring any specific commercial media for live birth or clinical

pregnancy rates, highlighting the adequacy of most well-designed embryo culture formulations for supporting successful ART cycles. Furthermore, comprehensive evaluation of commercial media compositions, as reported by Morbeck *et al.*, 2014 [5], reveals significant variability in nutrients and metabolic substrates such as amino acids, pyruvate, and lactate, yet these chemical differences have not been consistently associated with distinct reproductive outcomes.

Recent systematic reviews and meta-analyses of randomized controlled trials, including those by Bick *et al.* [8] and others, corroborate that no specific culture media can be regarded as universally superior, both in terms of live birth and birth weight when evaluated across diverse clinical scenarios [8] [15]. Differences in birth weight or perinatal parameters linked to media selection are generally modest and inconsistently reported, further reinforcing the notion that media selection can be guided by local availability, cost, and laboratory workflow, without compromising clinical efficacy or embryo viability.

Importantly, a growing body of evidence from animal studies and human ART validates the feasibility of using indigenous or locally formulated media as effective substitutes for commercial brands, particularly when resource optimization is necessary [16]. The results of the current investigation—showing parity between indigenous and commercially available culture media for fertilization, embryo development, blastocyst yield, and pregnancy rates—strongly support the clinical viability and cost-effectiveness of indigenous media formulations in ICSI practice. Future research should focus on the long-term health outcomes of children conceived using different culture media, as well as the potential personalization of media composition based on patient-specific metabolic and genetic profiles. Continued multi-center studies and transparent reporting will be critical in refining ART protocols to maximize both clinical success and safety.

Authors' Contributions

RR designed the study; RR and WT conducted the laboratory work; WT, AGM, and VAA wrote the manuscript. WT, and TNA performed the statistical analysis. All authors reviewed and approved the final manuscript.

Consent to Publication

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Conflicts of Interest

The authors declare that they do not have any conflicts of interest.

References

[1] Verma, D., Kaur, H., Chaudhary, A. and Verma, J. (2022) History of Human *In- Vitro*

Fertilization (IVF) and Assisted Reproduction Techniques (ART). *International Journal of Scientific Research in Modern Science and Technology*, **1**, 18-27.

[2] Gruber, I. and Klein, M. (2011) Embryo Culture Media for Human IVF: Which Possibilities Exist? *Journal of the Turkish German Gynecological Association*, **12**, 110-117. https://doi.org/10.5152/jtgga.2011.25

[3] Simopoulou, M., Sfakianoudis, K., Rapani, A., Giannelou, P., Anifandis, G., Bolaris, S., Pantou, A., Lambropoulou, M., Pappas, A., Deligeoroglou, E. and Pantos, K. (2018) Considerations Regarding Embryo Culture Conditions: From Media to Epigenetics. *In Vivo*, **32**, 451-460.

[4] van Duijn, L., Rousian, M., Kramer, C.S., van Marion, E.S., Willemsen, S.P., Speksnijder, J.P., *et al.* (2022) The Impact of Culture Medium on Morphokinetics of Cleavage Stage Embryos: An Observational Study. *Reproductive Sciences*, **29**, 2179-2189. https://doi.org/10.1007/s43032-022-00962-7

[5] Morbeck, D.E., Krisher, R.L., Herrick, J.R., Baumann, N.A., Matern, D. and Moyer, T. (2014) Composition of Commercial Media Used for Human Embryo Culture. *Fertility and Sterility*, **102**, 759-766.e9. https://doi.org/10.1016/j.fertnstert.2014.05.043

[6] Parry, B. and Ghoshal, R. (2022) Reproductive Empires and Perverse Markets: Unpacking the Paradoxical Dynamics of ART Market Expansion in Non-Urban India and Beyond. *Catalyst*: *Feminism*, *Theory*, *Technoscience*, **8**. https://doi.org/10.28968/cftt.v8i1.35188

[7] Ombelet, W., Van Blerkom, J., Boshoff, G., Huyser, C., Lopes, F., Nargund, G., *et al.* (2025) Now Is the Time to Introduce New Innovative Assisted Reproduction Methods to Implement Accessible, Affordable, and Demonstrably Successful Advanced Infertility Services in Resource-Poor Countries. *Human Reproduction Open*, **2025**, hoaf001. https://doi.org/10.1093/hropen/hoaf001

[8] Bick, L., Nielsen, A.S. and Knudsen, U.B. (2021) Embryo Culture Media Influence on Live Birth Rate and Birthweight after IVF/ICSI: A Systematic Review Comparing Vitrolife G5 Media to Other Common Culture Media. *JBRA Assisted Reproduction*, **25** 480-492. https://doi.org/10.5935/1518-0557.20200099

[9] Isaac, E. (2024) Establishment of a Novel Culture Medium for Growing Cattle Embryos beyond the Blastocyst Stage. Master's Thesis, Victoria University of Wellington.

[10] Glujovsky, D., Quinteiro Retamar, A.M., Alvarez Sedo, C.R., Ciapponi, A., Cornelisse, S. and Blake, D. (2022) Cleavage-Stage versus Blastocyst-Stage Embryo Transfer in Assisted Reproductive Technology. *Cochrane Database of Systematic Reviews*, No. 5, CD002118. https://doi.org/10.1002/14651858.cd002118.pub6

[11] Agarwal, A., Maldonado Rosas, I., Anagnostopoulou, C., Cannarella, R., Boitrelle, F., Munoz, L.V., *et al.* (2022) Oxidative Stress and Assisted Reproduction: A Comprehensive Review of Its Pathophysiological Role and Strategies for Optimizing Embryo Culture Environment. *Antioxidants*, **11**, Article 477. https://doi.org/10.3390/antiox11030477

[12] Filali, M., Hesters, L., Fanchin, R., Tachdjian, G., Frydman, R. and Frydman, N. (2008) Retrospective Comparison of Two Media for *In-Vitro* Maturation of Oocytes. *Reproductive BioMedicine Online*, **16**, 250-256. https://doi.org/10.1016/s1472-6483(10)60582-2

[13] Iratxe, L.P., Gutiérrez-Romero, J.M., Mangano, A.A. and Calero-Ruiz, M.M. (2018) Comparison of Two Commercial Embryo Culture Media (SAGE-1 Step Single Media vs. G1-PLUS™/G2-PLUS™ Sequential Media): Influence on *in Vitro* Fertilization Out-

comes and Human Embryo Quality. *JBRA Assisted Reproduction*, **22**, 128-133.

[14] Mantikou, E., Youssef, M.A.F.M., van Wely, M., van der Veen, F., Al-Inany, H.G., Repping, S., *et al.* (2013) Embryo Culture Media and IVF/ICSI Success Rates: A Systematic Review. *Human Reproduction Update*, **19**, 210-220. https://doi.org/10.1093/humupd/dms061

[15] Chronopoulou, E. and Harper, J.C. (2014) IVF Culture Media: Past, Present and Future. *Human Reproduction Update*, **21**, 39-55. https://doi.org/10.1093/humupd/dmu040

[16] Singha, J.K., Bhuiyan, M.M.U., Rahman, M.M. and Bari, F.Y. (2015) Comparison of Culture Media for *in Vitro* Maturation of Oocytes of Indigenous Zebu Cows in Bangladesh. *Journal of Animal Reproduction and Biotechnology*, **30**, 327-333. https://doi.org/10.12750/jet.2015.30.4.327