https://doi.org/10.32441/kjps.06.01.p6



# Al-Kitab Journal for Pure Sciences

ISSN: 2617-1260 (print), 2617-8141(online) www.kjps.isnra.org



# Studying the IVF Laboratory Performance Indicators the Vienna Consensus 2017 for the High Institute According to Diagnosis and Assisted Reproductive for Infertility Technologies, Al-Nahrain University, Iraq

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**Citation:** Hussein ZA, Rahim AI, Abdul-Hameed WA. Studying the IVF Laboratory Performance Indicators According to the Vienna Consensus 2017 for the High Institute for Infertility Diagnosis and Assisted Reproductive Technologies, Al-Nahrain University, Iraq. *Al-Kitab Pure Sci KJPS*. 2022; 6(1): 65-77. https://doi.org/10.32441/kjps.06.01.p6.

**Article History** 

Received Accepted Available online June 7, 2022 August 25, 2022 September 30, 2022

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#### **Abstract:**

**Background**: Performance indicators are used to assess patient safety, efficacy, equity, patient-centeredness, punctuality, and efficiency. The benchmark values for each Key Performance Indicator are aspirational values, and the minimum performance level values are the number of fertilized oocytes on Day 1 and the Normal Fertilization Rate, respectively (presence of 2Pro Nucleus and 2Polar Body measured at 17 h post-injection) as a Failed fertilization rate is calculated as the proportion of IVF cycles (excluding cycles with intracytoplasmic injection) on Day 1 (17 hours after insemination) with no signs of pregnancy.

During fertilization (i.e., 0 oocytes with 2Pro Nucleus). The percentage of zygotes on Day 2 (44 hours after insemination) is known as the cleavage rate, and it can suggest an issue with sperm quality (sperm function, oocyte activation, and gamete receptors), sperm processing, or the quantity of spermatozoa used for insemination. which cleaves to create embryos. The

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percentage of cleaved embryos per successfully fertilized egg that are at the 4-cell stage on Day 2 (44 hours post-insemination) or at the 8-cell stage on Day 3 (68 hours postinsemination) is known as the embryo development rate. This evaluates the viability and quality of the embryos as well as the capacity of the culture system to promote cleavage at the necessary stages. The critical factor is the proportion of blastocysts observed at 116 hours after insemination as a function of the number of correctly fertilized oocytes. Measures of performance blastocyst development rate. The viability of the embryo as well as the culture system's capacity to support blastocyst formation from fertilized oocytes (i.e., the formation of an intracellular mass and a blastocoele cavity) are both determined by this factor. It should be noted that this phrase only considers blastocyst formation and not blastocyst stage or quality. The damage rate is the proportion of oocytes that are injured or have deteriorated by the time of fertilization assessment on Day 1 as a result of the intracytoplasmic injection. The percentage of biopsied and tubed/fixed samples where DNA is found represents the success rate of the biopsy. It serves as a gauge of the embryologists' ability to transfer biopsied samples to test tubes, as shown by successful DNA amplification. The number of gestational sacs divided by the total number of transplanted embryos is how one calculates the implantation rate, which is dependent on the cleavage stage. By dividing the number of gestational sacs by the total number of transplanted blastocysts, the implantation KPI (blastocyst stage) is calculated.

#### Aim

Compare the annual results of our institute with the ESHRE-defined international KPI, the Performance Indicators (Fertilization rate, cleavage rate, development day 2, development day 3, blastocyst rate, blastocyst cryosurvival rate, damage rate, successful biopsy rate, implantation rate depends on cleavage stage, implantation rate depends on blastocyst stage).

Patients and Methods: From November 2015 to December 2021, 699 infertile couples who were having intracytoplasmic sperm injection were included in a retrospective study done at the high institution for infertility diagnosis and assisted reproductive technologies at Al Nahrain University in Baghdad, Iraq. The information gathered from the lab and the archive room was classified and divided. Comparing each year to the previous years as well as comparing with the performance indicators (fertilization rate, cleavage rate, development day 2, development day 3, blastocyst rate, blastocyst cryosurvival rate, damage rate, success rate of biopsy, implantation rate dependent on cleavage stage, implantation rate dependent on

blastocyst stage), as well as with ESHRE. Except for the successful biopsy rate and implantation rate, all markers were identified in this investigation.

#### **Results**

The fertilization and cleavage rates closely to ESHRE's Key Performance Indicators. The outcomes from days two and three were also close to the ESHRE competency and benchmark standards. Comparison of the mean blastocyst rate revealed a substantial amount of fluctuation, with the highest year being 2016 and the lowest being 2019. 2015 and 2016 are the highest and lowest years for a blastocyst of cryosurvival, respectively. 2020 and 2021 both saw the highest ICSI damage rate. 2015 and 2020 are the highest and lowest pregnancy result years respectively.

**Keywords:** KPI, ICSI, Pregnancy rate.

# دراسة مؤشرات أداء مختبر التلقيح الاصطناعي حسب إجماع فيينا 2017 للمعهد العالي للعقم التشخيص والمساعدة على الإنجاب، جامعة النهربن، العراق

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# الخلاصة

تُستخدم مؤشرات الأداء لتقييم سلامة المريض والفعالية والإنصاف والتركيز على المريض والالتزام بالمواعيد والكفاءة. القيم المعيارية لكل مؤشر أداء رئيسي هي قيم طموحة ، والحد الأدنى لقيم مستوى الأداء هو عدد البويضات المخصبة في اليوم الأول ومعدل الإخصاب الطبيعي ، على التوالي ( نواه عدد 2 والجسم القطبي تم قياسهما في 17 ساعة بعد الحقن) كمعدل الإخصاب الفاشل يتم حسابه كنسبة من دورات التلقيح الاصطناعي (باستثناء دورات الحقن داخل المجهري) في اليوم الأول ( 17 ساعة بعد التلقيح) مع عدم وجود علامات الحمل (علماء ألفا في الطب التناسلي المنظمة العالمية للأجنة والخصوبة) أثناء الإخصاب تُعرف النسبة المئوية للحيوانات الملقحة في اليوم الثاني (44 ساعة بعد التلقيح) بمعدل الانقسام ، ويمكن أن تشير إلى مشكلة تتعلق بجودة الحيوانات المنوية (وظيفة الحيوانات المنوية ، وتفعيل البويضات ، ومستقبلات الأمشاج) ، أو معالجة الحيوانات المنوية المستخدمة للتلقيح. التي تلتصق لتكوين الأجنة [1]. تُعرف النسبة المئوية للأجنة المشقوقة لكل بويضة مخصبة بنجاح في المرحلة المكونة من 4 خلايا في اليوم الثاني (44 ساعة بعد التلقيح) أو في المرحلة المكونة من 8 خلايا في اليوم الثاني (44 ساعة بعد التلقيح) وجودة المرحلة المكونة من 8 خلايا في اليوم الثائي قي اليوم الثالث (68 ساعة بعد التلقيح) باسم تطور الجنين معدل. يقوم هذا بتقييم صلاحية وجودة المرحلة المكونة من 8 خلايا في اليوم الثاني (44 ساعة بعد التلقيح) وجودة المرحلة المكونة من 8 خلايا في اليوم الثالث (68 ساعة بعد التلقيح) باسم تطور الجنين معدل. يقوم هذا بتقييم صلاحية وجودة

الأجنة وكذلك قدرة نظام الاستزراع على تعزيز الانقسام في المراحل اللازمة. العامل الحاسم هو نسبة الأكياس الأريمية التي لوحظت بعد 116 ساعة من التلقيح كدالة لعدد البويضات المخصبة بشكل صحيح.

مقاييس أداء معدل تطور الكيسة الأريمية. يتم تحديد قابلية بقاء الجنين وكذلك قدرة نظام الاستزراع على دعم تكوين الكيسة الأريمية من البويضات المخصبة (أي تكوين كتلة داخل الخلايا وتجويف القيلة الأريمية) بواسطة هذا العامل. وتجدر الإشارة إلى أن هذه العبارة تتناول فقط تكوين الكيسة الأريمية وليس مرحلة الكيسة الأريمية أو جودتها. معدل الضرر هو نسبة البويضات المصابة أو التي تدهورت في وقت تقييم الإخصاب في اليوم الأول نتيجة الحقن داخل الهيولى. تمثل النسبة المئوية للعينات المأخوذة من الخزعة والأنابيب / الثابتة حيث تم العثور على الحمض النووي معدل نجاح الخزعة. إنه بمثابة مقياس لقدرة علماء الأجنة على نقل العينات المأخوذة من الخزعة إلى أنابيب الاختبار ، كما يتضح من تضخيم الحمض النووي الناجح. عدد أكياس الحمل مقسومًا على العدد الإجمالي للأجنة المزروعة هو كيفية حساب معدل الانغراس ، والذي يعتمد على مرحلة الانقسام بقسمة عدد أكياس الحمل على العدد الإجمالي للكيسات الأريمية المزروعة ، يتم حساب مؤشر الأداء الرئيسي (مرحلة الكيسة الأريمية).

#### الغرض

مقارنة النتائج السنوية لمعهدنا مع مؤشرات الأداء الرئيسية الدولية المحددة من قبل ايشري ومؤشرات الأداء (معدل الإخصاب، معدل الانقسام، يوم التطوير 2 ، يوم التطوير 3 ، معدل الكيسة الأريمية، معدل النقاء على قيد الحياة في الكيسة الأريمية، معدل الضرر ، معدل الخزعة الناجح ، معدل الزرع يعتمد في مرحلة الانقسام، يعتمد معدل الانغراس على مرحلة الكيسة الأريمية)، المرضى وطرق العلاج: من تشرين الثاني (نوفمبر) 2015 إلى كانون الأول (ديسمبر) 2021 ، تم تضمين الكيسة الأريمية)، المرضى وطرق العلاج: من تشرين الثاني (نوفمبر) 2015 إلى كانون الأول (ديسمبر) 699 من الأزواج المصابين بالعقم والذين كانوا يخضعون لحقن الحيوانات المنوية داخل الهيولى في دراسة بأثر رجعي أجريت في المؤسسة العليا لتشخيص العقم وتقنيات الإنجاب المساعدة في جامعة النهرين في بغداد ، العراق. تم تصنيف وتقسيم المعلومات التي تم جمعها من المختبر و غرفة الأرشيف. مقارنة كل عام بالسنوات السابقة وكذلك المقارنة مع مؤشرات الأداء (معدل الإخصاب ، معدل الانقسام ، يوم التطوير 2 ، يوم التطوير 3 ، معدل الكيسة الأريمية ، معدل بقاء الكيسة الأريمية بالنتراس على مدل الضرر ، معدل الانتراء معدل الانغراس يعتمد على الانقسام المرحلة ، ويعتمد معدل الانغراس على مرحلة الكيسة الأريمية) ، وكذلك مع . باستثناء معدل الخزعة الناجح ومعدل الزرع ، تم تحديد جميع العلامات في هذا التحقيق مرحلة الكيسة الأريمية) ، وكذلك مع . باستثناء معدل الخزعة الناجح ومعدل الزرع ، تم تحديد جميع العلامات في هذا التحقيق

# النتائج

معدلات الإخصاب والانقسام قريبة من مؤشرات الأداء الرئيسية لـ ESHRE. كانت نتائج اليومين الثاني والثالث قريبة أيضًا من معايير الكفاءة والمعايير ESHRE. كشفت مقارنة متوسط معدل الكيسة الأريمية عن قدر كبير من التقلبات ، حيث كان أعلى عام هو عام 2016 وأدنى عام هو عام 2019 ، يُعد عامي 2015 و 2016 هما الأعلى والأدنى بالنسبة إلى الكيسة الأريمية للبقاء بالتبريد ، على التوالي. شهد كل من عامي 2020 و 2021 أعلى معدل ضرر للحقن المجهري. 2015 و 2020 هما أعلى وأدنى نتيجة حمل على التوالي.

الكلمات المفتاحية: مؤشرات الأداء الرئيسية، حقن الحيوانات المنوية داخل السايتو بلازم، الحمل.

# 1. INTRODUCTION:

Infertility is the medically recognized inability to get pregnant after at least a year of unbroken, unprotected sexual activity. [1, 2] estimates that 8–12% of couples who are of reproductive age will be impacted. Demographers describe infertility as a woman's inability to conceive a live child despite engaging in sexual activity and without using contraception [3]. Infertility for women over 35 was previously defined as the inability to conceive after at least six months or a year of unrestricted sexual engagement.

With the aid of assisted reproductive technology (ART), infertility may be treated (ART). In reproductive procedures, it describes both the male sperm and the female ovum. It works by removing the eggs from the lady. Embryos are produced when sperm and eggs are joined. After that, the embryos are returned to the woman's body. In vitro fertilization is the most widely used and successful kind of ART (IVF) Occasionally, ART procedures may involve the use of frozen embryos, donor eggs, or sperm. Surrogacy or the use of a gestational carrier may also be used. A woman who uses her male partner's sperm to carry the couple's kid is known as a surrogate. Pregnancy occurs in the gestational carrier as a result of the union of the male and female partners' sperm and eggs. [4-6].

# **Types of ART:**

Different ART procedures employ various methodologies and reproductive cells. A doctor can advise on the most suitable ART method based on the situation. The most common technique of conception is by in vitro fertilization [7]. One of the top methods for treating infertility is ICSI, ICSI, or intracytoplasmic sperm injection are all names for the procedure. One live sperm is injected into the center of an egg by means of this procedure.

The process is completed by stimulating the release of a significant number of mature eggs from the female partner's ovaries using fertility medications. The eggs are then carefully removed from the uterus using vaginal ultrasonography and stored in an embryology facility. To prepare the sperm sample, centrifugation is utilized, which involves spinning sperm cells in a certain medium. The majority of the living and dead sperm can then be distinguished from debris in this way. The embryologist will then use a glass needle

to place the last sperm into the egg [8]. The international organization ESHRE created Performance Indicators to be used in the laboratory to carry out the ICSI process.

Because they enable evaluation of the efficacy, efficiency, equity, and patient-centeredness of treatment, performance indicators (PIs) are a crucial part of the quality management system (QMS) (ESHRE Guideline Group on Good Practice in IVF[9,10]. Currently, laboratories using assisted reproductive technology (ART) lack performance indicators (PIs) and have limited published data [11]. The objectives of this international workshop were to reach consensus on the key performance indicators (KPIs) for oocyte and embryo cryopreservation using slow freezing or vitrification, as well as on the minimum performance level values for each KPI, which represent fundamental competency, and aspirational benchmark values for each KPI, which represent best practice goals. This study provides overviews of current practice and important standards for creating KPIs. All 14 KPIs have benchmarks available [12].

#### KPIs IN THE ART LABORATORY

Because of the work that is done with gametes and embryos in the lab, the ART technique is most crucial there. Above all, it is crucial to take into account these strategies and the surrounding surroundings [13].

# 2. Patients and Methods

# Material

The embryologist is responsible for keeping the books' notes neat and organized. Paper and hard copies were used for the data collection process from the IVF laboratory. These notebooks are kept safe from any potential hazards, such as fire, water, and electrical sources. The information gathered from the archive room is also kept on paper, albeit it is not organized enough to guarantee finding anything. Data was gathered to be compared to the international organization ESHRE's KPI.

#### Methods

At the start of the study, a form with information was given; complete it as directed. Along with his address, education, occupation, whether or not he smokes, what sort of smoking he does, and any illnesses he may have, the husband's name, height, weight, blood

type, absence day, volume of semen, concentration, motility, agglutination, and round cell are all mentioned on this form. What previous health issues, like diabetes or high blood pressure, did he have? How many procedures has he had in the past, Name, weight, blood type, age, and hormone analyses for FSH, LH, prolactin, and AMH (Anti Mullerian hormone), among other details, were found.

It's also important to know details about embryos, such as how many are implanted every day, how many pro nuclei or embryos are injected, how many follicles, oocytes, or ruptured oocytes, germinal vesicles, MI, or MIII, how many are retrieved, when those are transferred, and how many are of different grades. This study The IVF operation room and the archives should work together to gather all the data. 2015, 2016, 2017, 2018, 2019, 2020, and 2021 were the years for which data was gathered. About 699 instances made up the data. was unable to find certain names or files, possibly because they had been relocated from the operating room to the archive room to display the medical reports.

# 3-Result

# Key performance indicators compared according to year

**CSI normal fertilization rate: Table 1** compares the normal fertilization rate for ICSI according to year. Because the categorical feature (cleavage rate) is a constant and not a variable, statistical analysis cannot be done with respect to competency values of 65% because the rate in all years is more than 65%. Because the categorical characteristic (cleavage rate) is a constant and not a variable, the rate in all years exceeds the benchmark value of 80%, making statistical analysis impossible.

Table 1: Comparison of ICSI normal fertilization rate according to year

| Characteristic              | 2015  |     | 2016 |     | 2017  |     | 2018   |     | 2019  |     | 2020 |     | 2021  |     | Total |     |
|-----------------------------|-------|-----|------|-----|-------|-----|--------|-----|-------|-----|------|-----|-------|-----|-------|-----|
| INFRC<br>(Competency value) | n= 21 |     | n=73 |     | n=144 |     | n= 216 |     | n=231 |     | n=27 |     | n=127 |     | n=839 |     |
| ≥ 65 %                      | 21    | 100 | 73   | 100 | 144   | 100 | 216    | 100 | 231   | 100 | 27   | 100 | 127   | 100 | 839   | 100 |
| <65 %                       | 0     | 0   | 0    | 0   | 0     | 0   | 0      | 0   | 0     | 0   | 0    | 0   | 0     | 0   | 0     | 0   |
| INFRB<br>(Benchmark value)  | n= 2  | 21  | n=7  | 3   | n=144 |     | n= 21  | .6  | n=23  | 1   | n=2  | 7   | n=12' | 7   | n=839 | 9   |
| ≥ 80 %                      | 21    | 100 | 73   | 100 | 144   | 100 | 216    | 100 | 231   | 100 | 27   | 100 | 127   | 100 | 839   | 100 |
| <80 %                       | 0     | 0   | 0    | 0   | 0     | 0   | 0      | 0   | 0     | 0   | 0    | 0   | 0     | 0   | 0     | 0   |

# Cleavage rate:

**Table 2** compares the cleavage rate with time according to year. Because the categorical feature (cleavage rate) is a constant and not a variable, the rate in all years is greater than 95% with respect to the competency value of less than 95%, making statistical analysis impossible.

Because the categorical characteristic (cleavage rate) is a constant and not a variable, the rate in all years exceeds the benchmark value of 99%, making statistical analysis impossible.

| Characteristic            | 2015  | 5   | 2010 | 5   | 2017  |     | 2018   |     | 2019  |     | 2020 | 0   | 2021  |     | Total |     |
|---------------------------|-------|-----|------|-----|-------|-----|--------|-----|-------|-----|------|-----|-------|-----|-------|-----|
| CRC<br>(Competency value) | n= 24 |     | n=78 |     | n=148 |     | n= 216 |     | n=229 |     | n=27 |     | n=111 |     | n=833 |     |
| ≥ 95 %                    | 24    | 100 | 78   | 100 | 148   | 100 | 216    | 100 | 229   | 100 | 27   | 100 | 111   | 100 | 833   | 100 |
| <95 %                     | 0     | 0   | 0    | 0   | 0     | 0   | 0      | 0   | 0     | 0   | 0    | 0   | 0     | 0   | 0     | 0   |
| CRB<br>(Benchmark value)  | n= 2  | 24  | n=7  | 8   | n=148 |     | n= 21  | 6   | n=22  | 9   | n=2  | 7   | n=11  | 1   | n=83  | 3   |
| ≥ 99 %                    | 24    | 100 | 78   | 100 | 148   | 100 | 216    | 100 | 229   | 100 | 27   | 100 | 111   | 100 | 833   | 100 |
| <99 %                     | 0     | 0   | 0    | 0   | 0     | 0   | 0      | 0   | 0     | 0   | 0    | 0   | 0     | 0   | 0     | 0   |

Table 2 Comparison cleavage rate according to year

**Day 2 embryo development rate:** In **Table 3**, the rate of embryo development on day 2 is compared by year. With regard to Competency Value, the rate of 50% was between 67.2% and 86.7%, and the difference was not statistically significant (p > 0.05). In terms of benchmark value, the rate of 80% varied from 25.9% to 63.3%, and the difference between 2015 and 2020 was not significant (p > 0.05); nevertheless, a substantial decline was found in the year 2021 (p = 0.0).

Characteristic 2015 2016 2017 2018 2019 2020 2021 Total **D2EDRC** n= 4 n= 30 n= 33 n= 137 n= 58 n = 70n= 22 n= 353 (Competency value) 113 82.5 18 ≥ 50 % 75.0 26 86.7 27 81.8 72.9 81.8 39 67.2 78.2 1 25.0 13.3 6 18.2 19 27.1 24 17.5 4 18.2 19 32.8 77 21.8 <50 % 0.536 0.599 0.322 0.106 0.940 0.198 D2EDRB n = 70n= 4 n=30n=33n= 137 n= 22 n= 353 n= 58 (Benchmark value) 13 ≥ 80 % 2 50.0 19 63.3 39.4 31 44.3 71 51.8 11 50.0 15 25.9 162 45.8 2 192 <80 % 50.0 11 36.7 20 60.6 39 55.7 66 48.2 11 50.0 43 74.1 54.2 0.874 0.058 0.305 0.606 0.6400.040 \* NS NS NS NS NS

Table 3: Comparison of day 2 embryo development rate according to year

Day 3 embryo development rate: Table 4 compares the pace of embryo development on day 3 according to year. The rate of 45% for Competency Value ranged from 52.6% to 81.0%, and the difference was not statistically significant (p > 0.05). Regarding Benchmark value, the rate of  $\geq 70$  % was ranging from 20.0 % to 69.4 % and the difference was among

years 2015 through 2017 was not significant (p > 0.05); but significant reduction was reported in year 2019 (p = 0.007), but later on the fluctuation in rate became not significant (p > 0.05).

Table 4: Comparison of day 3 embryo development rate according to year

| Characteristic               | 201  | 5  | 2010        | 5         | 2017        |        | 2018        |        | 2019        |        | 2020        | 0    | 202         | 1    | Total  | l    |
|------------------------------|------|----|-------------|-----------|-------------|--------|-------------|--------|-------------|--------|-------------|------|-------------|------|--------|------|
| D3EDRC<br>(Competency value) | n= 2 | 25 | n= 7        | n= 71     |             | n= 131 |             | n= 188 |             | n= 211 |             | 27   | n= 96       |      | n= 749 |      |
| ≥ 45 %                       | 20   | 80 | 57          | 57 80.3   |             | 80.9   | 141         | 75.0   | 169         | 80.1   | 21          | 77.8 | 59          | 61.5 | 573    | 76.5 |
| <45 %                        | 5    | 20 | 14          | 19.7      | 25          | 19.1   | 47          | 25.0   | 42          | 19.9   | 6           | 22.2 | 37          | 38.5 | 176    | 23.5 |
|                              |      |    | 0.976<br>NS |           | 0.913<br>NS |        | 0.214<br>NS |        | 0.222<br>NS |        | 0.778<br>NS |      | 0.116<br>NS |      |        |      |
| D3EDRB<br>(Benchmark value)  | n= 2 | 25 | n= 7        | <b>'1</b> | n= 131      |        | n= 18       | 88     | n= 21       | 1      | n= 2        | 27   | n= 96       |      | n= 74  | 19   |
| ≥ 70 %                       | 15   | 60 | 43          | 60.6      | 81          | 61.8   | 116         | 61.7   | 102         | 48.3   | 12          | 44.4 | 30          | 31.3 | 399    | 53.3 |
| <70 %                        | 10   | 40 | 28          | 28 39.4   |             | 38.2   | 72          | 38.3   | 109         | 51.7   | 15          | 55.6 | 66          | 68.8 | 350    | 46.7 |
|                              |      |    | 0.96<br>NS  | 0         | 0.860<br>NS |        | 0.981<br>NS |        | 0.007 **    |        | 0.703<br>NS |      | 0.201<br>NS |      |        |      |

**Blastocyst development rate: Table 5** displays a comparison of the Blastocyst formation rate by year. When it came to competency value, the rate of 40% ranged from 0% to 90.0%; there was a significant difference between 2015 and 2016 (p = 0.016), but no significant change was observed in subsequent years (p > 0.05). With regards to the benchmark value, the rate of 60% ranged from 0% to 75.0%; however, the difference was not statistically significant (p > 0.05).

Table 5: Comparison of Blastocyst development according to year

| Characteristic             | 201   | 15    | 201         | 16      | 201         | 17          | 2018        |             | 2019        |      | 202   | 20  | 202         | 21   | Tota   | ıl   |
|----------------------------|-------|-------|-------------|---------|-------------|-------------|-------------|-------------|-------------|------|-------|-----|-------------|------|--------|------|
| BDRC<br>(Competency value) | n = 2 |       | n = 8       |         | n = 12      |             | n = 11      |             | n = 21      |      | n = 0 |     | n = 6       |      | n = 60 |      |
| ≥ 40 %                     | 0     | 0.0   | 7           | 7 87.5  |             | 66.7        | 10          | 90.9        | 15          | 71.4 | 0     | 0.0 | 4           | 66.7 | 44     | 73.3 |
| <40 %                      | 2     | 100.0 | 1           | 12.5    | 4           | 33.3        | 1           | 9.1         | 6           | 28.6 | 0     | 0.0 | 2           | 33.3 | 16     | 26.7 |
|                            |       |       | 0.0         | 0.016 * |             | 0.292<br>NS |             | 0.159<br>NS |             | 5    |       |     | 0.822<br>NS |      |        |      |
| BDRB<br>(Benchmark value)  | n=    | : 2   | n=          | : 8     | n = 12      |             | n = 11      |             | n = 21      |      | n = 0 |     | n = 6       |      | n = 60 |      |
| ≥ 60 %                     | 0     | 0.0   | 6           | 75.0    | 7           | 58.3        | 9           | 81.8        | 11          | 52.4 | 0     | 0.0 | 4           | 66.7 | 37     | 61.7 |
| <60 %                      | 2     | 100.0 | 2           | 2 25.0  |             | 41.7        | 2           | 18.2        | 10          | 47.6 | 0     | 0.0 | 2           | 33.3 | 23     | 38.3 |
|                            |       |       | 0.053<br>NS |         | 0.444<br>NS |             | 0.221<br>NS |             | 0.102<br>NS |      |       |     | 0.535<br>NS |      |        |      |

**Blastocyst cryosurvival rate: Table 6** presents a comparison of the Blastocyst cryosurvival rate by year. When it came to competency value, the rate of 90% ranged from 50% to 100%; there was no significant difference between 2015 and 2016 (p = 0.747), but a significant decline was observed in the next year (p = 0.021), and the rate fluctuation in subsequent years was not significant (p > 0.05). The benchmark value ranged from 50% to 91.7%, but the difference was not statistically significant (p > 0.05).

2015 2016 2019 Characteristic 2017 2018 2020 2021 Total BCSRC n = 2n = 8n = 12n = 11n = 21n = 0n = 6 n = 49 (Competency value) 5 100.0 85.7 0 66.7 ≥ 90 % 50.0 62.5 12 11 100 18 0.0 4 40 81.6 1 <90 % 50.0 3 37.5 0 0.0 0 0 3 14.3 0 0.0 2 33.3 18.4 1 0.747 C 0.188 C 0.289 C 0.021 C \* NS NS NS **BCSRB** n = 2n = 8n = 12n = 11n = 21n = 0n = 6n = 49(Benchmark value) 1 5 85.7 0 4 66.7 ≥99 % 50.0 62.5 11 91.7 10 90.9 18 0.0 39 79.6 3 3 0 <99 % 50.0 37.5 8.3 1 9.1 14.3 0.0 33.3 10 20.4 0.747 C 0.110 C 0.949 C 0.673 C 0.289 C

Table 6: Comparison of Blastocyst cryosurvival rate according to year

**ICSI damage rate:** In **Table 7**, the damage rate for ICSI is compared by year. ICSI damage rates greater than 10% ranged from 7.4% to 25.9%, with an upward trend over time. Year 2018 shown a significant increase in this rate in contrast to the year before (p = 0.012). When comparing benchmark values of > 5%, the rate varied from 2.7% to 26.6% with an upward trend over time; the level of p-value was greater than 0.05 when comparing succeeding years to prior years; however, some p-values, like 0.080 and 0.052, were extremely close to the threshold of significance of 0.05.

Table 7: Comparison of ICSI damage rate according to year

| Characteristic            | 2  | 015  | 2  | 2016       |             | )17    | 20  | )18    | 20  | 19        | 2           | 020   | 20          | )21    | Total |      |
|---------------------------|----|------|----|------------|-------------|--------|-----|--------|-----|-----------|-------------|-------|-------------|--------|-------|------|
| IDR<br>(Competency value) | n: | = 27 | n: | n= 79      |             | n= 172 |     | n= 216 |     | n= 247    |             | n= 30 |             | n= 139 |       | 910  |
| ≤ 10 %                    | 25 | 92.6 | 69 | 87.3       | 159         | 92.4   | 184 | 85.2   | 208 | 84.2      | 27          | 90.0  | 103         | 74.1   | 775   | 85.2 |
| >10 %                     | 2  | 7.4  | 10 | 12.7       | 13          | 7.6    | 32  | 14.8   | 39  | 15.8      | 3           | 10.0  | 36          | 25.9   | 135   | 14.8 |
| <i>p</i> -value           |    |      |    | .457<br>NS | 0.193<br>NS |        | 0.0 | 27 *   |     | 772<br>IS | 0.404<br>NS |       | 0.061<br>NS |        |       |      |
| IDR<br>(Benchmark value)  | n: | = 27 | n: | n= 79      |             | n= 172 |     | 216    | n=  | 247       | n           | = 30  | n=          | 139    | n=    | 910  |
| ≤ 5 %                     | 25 | 92.6 | 69 | 87.3       | 154         | 89.5   | 180 | 83.3   | 205 | 83.0      | 27          | 90.0  | 102         | 73.4   | 762   | 83.7 |

| >5 %            | 2 | 7.4 | 10 | 12.7        | 18 | 10.5      | 36 | 16.7      | 42 | 17.0      | 3 | 10.0       | 37 | 26.6      | 148 | 16.3 |
|-----------------|---|-----|----|-------------|----|-----------|----|-----------|----|-----------|---|------------|----|-----------|-----|------|
| <i>p</i> -value |   |     |    | 0.457<br>NS |    | 508<br>IS |    | 1S<br>080 |    | 923<br>IS |   | .326<br>NS |    | 052<br>NS |     |      |

# 4. Discussion

# Comparison of ICSI's average fertilization rate over time:

Compares the typical ICSI fertilization rate by year. All years' rates above the competency value of 65 percent since the category feature (cleavage rate) is a constant and not a variable, making statistical analysis impossible. Because the categorical characteristic (cleavage rate) is a constant and not a variable, the rate in all years exceeds the benchmark value of 80%, making statistical analysis impossible. The outcomes were quite close to the ESHRE KPI.

# Comparison of the cleavage rate across years:

Compares the cleavage rate between years. Statistical analysis cannot be performed on these data because the categorical feature (cleavage rate), which has a competency value of 95%, is a constant and not a variable because the rate is always larger than 95%. Since the cleavage rate is a categorical trait and not a variable, it exceeds the benchmark figure of 99 percent every year, making statistical analysis impossible. The results closely matched the KPI for ESHRE.

# Development on day two is contrasted by year:

In terms of competency value, the range for the 50% rate was 67.2 to 86.7 percent, with no statistically significant difference (p > 0.05). The benchmark value's 80% rate ranged from 25.9 to 63.3 percent, and the difference between 2015 and 2020 was not statistically significant (p > 0.05); however, the year 2021 showed a significant reduction (p = 0.04). It is most likely due to the lack of instances in 2020. A comparison of annual rates of day 2 embryo development.

# Day 3 embryo development rates:

The rate of embryo development on day 3 is contrasted by year. In terms of competency value, the difference between the rates of 45 percent and 52.6 percent to 81.0 percent was not statistically significant (p > 0.05). Regarding the benchmark value, the rate of 70% ranged from 20.0 to 69.4%, and the variation between 2015 and 2017 was not significant (p > 0.05); however, a substantial reduction was seen in 2019 (p = 0.007), after which the rate fluctuation became not significant (p > 0.05). There are no specific causes, however one of the following possibilities could exist: Sperm abnormality and an intrinsic factor (nearly normal oocyte) (DNA fragmentation ,defect in centriole, origin of sperm). Incubator and media type (poor media quality) are both negative.

Blastocyst development rate comparison between years compares the Blastocyst formation rate by year. Regarding Competency value, the rate of 40% ranged from 0% to 90.0 %; there

was a significant difference between 2015 and 2016 (p = 0.016), but no significant change was observed in subsequent years (p > 0.05). Regarding Benchmark value, the rate of 60% ranged from 0 to 75.0 percent; nevertheless, the difference was not statistically significant (p > 0.05). The following are most likely the causes: low number of blastocyst cases because patients do not understand that the embryo develops to this stage and because the institute (doctors) does not encourage it.

# comparison of the Blastocyst cryosurvival rate between years.

A comparison of the Blastocyst cryosurvival rate by year. Between 2015 and 2016 there was no significant change (p = 0.747), but in 2017 there was a significant fall (p = 0.021), and the rate variation in the years after that was not significant (p > 0.05). The rate of 90% for Competency Value ranged from 50% to 100%. The rate of less than 99 percent varied from 50 to 91.7% in terms of benchmark value, however the variation was not statistically significant (p > 0.05). Age, weight, the wife's hormonal balance, oocyte and sperm quality, as well as her age and weight, are potential contributing factors.

# Comparison of ICSI damage rates between years

The damage rate for ICSI is contrasted by year. With an upward trend over time, the rate of ICSI damage rates greater than 10% ranged from 7.4 percent to 25.9 percent, and the year 2018 showed a noticeable increase in this rate compared to the year before (p = 0.012). The level of p-value was higher than 0.05 when comparing data from subsequent years to those from earlier years; yet, several p-values, such 0.080 and 0.052, were quite close to the level of significance of 0.05. The rate ranged from 2.7 percent to 26.6 percent with an increasing rate trend over time with respect to the benchmark value of > 5 percent.

# 5- Conclusions

The efficiency standard values, which are the minimum expected, the efficiency values that every laboratory should be able to achieve, and the efficiency values that can be used as best practice, were contrasted in this study. The outcomes are satisfactory and favorable.

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