Original Article

A Preliminary Experience of Integration of an Electronic Witness System, its Validation, Efficacy on Lab Performance, and Staff Satisfaction Assessment in a Busy Indian *in vitro* Fertilization Laboratory

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Abstract

Background: Electronic witness system (EWS) is one of the recent advancements in the field of *in vitro* fertilization (IVF) that uses radiofrequency identification (RFID) technology to monitor all critical work carried out in each stage of IVF procedures cycle. **Objective:** The main objective of the study was validation and integration of electronic witnessing system, assessment of its efficacy on lab performance, and staff satisfaction in a busy tertiary IVF center. **Materials and Methods:** The study data included analysis of 187 consecutive cycles for installation and validation of EWS. The laboratory outcomes were analyzed for development of good-quality embryos followed up for the pregnancy outcome. **Results:** A total of 751 RFIG tags were involved with 77 patient-assigned barcodes for the all the analyzed cycles. During validation of EWS, a total of 02 (0.46%) red flags were highlighted by EWS from pre-allocated tags within the frequency range of the reader. The maturation rate (83.1%), fertilization rate (74.3%), cleavage rate (93.5%), day 3 grade-A embryo development rate (64.6%), good grade blastocyst development rate (26.4%) were observed in EWS group that was comparable to other groups with no significant difference ($P > 0.005$). Frozen embryo transfer of EWS cases observed a clinical pregnancy rate (50.0%) that was higher than other groups though statistically not significant as sample size was small. **Conclusions:** Our preliminary study suggests that EWS does not affect the gametes, embryos, and pregnancy rate, however a larger randomized clinical trials should be undertaken to evaluate the safety and efficacy of EWS.

Keywords: *Assisted reproductive technology, biological mismatch, electronic witness system, infertility, in vitro fertilization, radio frequency identification technology*

Introduction

Infertility is a failure to achieve pregnancy even after 1 year of unprotected intercourse affecting around 8%–12% of couples worldwide. With the recent advancements in Assisted reproductive technology (ART), infertility treatment has become effective and is easily accessible now. It has given many healthy live births ever since its inception in 1978. Recently, there was news that shocked the medical fraternity and the patients all over the globe opting for infertility treatment. A lawsuit was filed against a California-based fertility clinic by a US couple of Asian

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descent alleging of *in vitro* fertilization (IVF) mix-up after women gave birth to two boys of non-Asian traits.[1] The first case of an ART mix-up was reported in the year 1987.[2] In ART, oocytes (egg) from women and sperms from husband are handled outside the human body and fertilized through a robust mechanism to avoid any rare biological mix-up. Traditionally, all the procedural steps are carefully witnessed manually by another trained embryologist also known as manual double witnessing. However, the mixing of gametes can sometimes happen usually referred to as "mix-up" which means the woman's egg or the man's sperm being mixed up with the unrelated gametes or an embryo is wrongly transferred into women that is completely unrelated to the couple. Though "mix-up" is a rare event, it may happen and could shatter the trust of the couples undergoing ART treatment on medical procedures and can destroy the reputation of a fertility clinic. The accidental use of incorrect gametes or embryos during ART procedures has been reported worldwide from IVF laboratories and is considered a rare event (<1%).[3,4]

There are few critical steps identified during the clinical and laboratory IVF procedures that have a high potential for mismatch of gametes and embryos. In the IVF process, the embryologist performs multiple steps starting from oocyte retrieval, sperm processing, egg denudation, intracytoplasmic sperm injection (ICSI) or insemination (IVF), fertilization, embryo transfer (ET) between dishes, ET in the patient, gamete or embryo vitrification or thawing of embryos, and embryo biopsy.[5] All these stages are prone to miscommunication and can lead to mix-ups even in the absence or presences of witnessing by a second embryologist known as manual double witnessing. Because the potential for human error is always present even experienced embryologists and clinical staff can sometimes commit mistakes. Therefore, there is an absolute need for the introduction of an electronic safety system or some kind of automation that could prevent such a mix-up of gametes or embryos.[6] Recent good practice guidelines for the practice of IVF laboratories by the European Society of Human Reproduction and Embryology have also recommended an electronic identification system to improve traceability and reducing IVF mix-ups with risk assessment before implementation in a clinical setting.[7]

Electronic witness system (EWS) is one of the recent advancements in IVF clinical practices that uses radiofrequency identification (RFID) technology and/or unique barcoded labels to monitor all critical work carried out in all stages of the IVF procedures cycle. RFID technology-based EWS uses RFID tags for tracking and recording patients' information and the biological samples during the entire IVF process. Unique barcoded labels-based EWS uses a barcode scanner to identify the patients and biological samples at every step of the IVF procedure. These systems help to decrease the risk of human error every time gametes are moved from one dish or tube to another and safeguard every step of the IVF cycle. EWS has two major advantages: firstly, it prevents embryologists from accidentally working on more than one patient's eggs or sperm at a time, and secondly, it marks each step thus preventing embryologists from omitting any key tasks in the process, thus ensuring that all the crucial steps are performed before moving to the next procedural following standard operating procedure. It identifies gametes that are monitored at every stage of the assisted reproductive technology (ART) cycle and simultaneously the system records every information regarding the cycle progress.[8] This system minimizes the chances of IVF mix-ups by tracking the transfers of gametes or embryos from one dish or tube to another following all procedural steps. The use of these electronic systems is rapidly extending to fertility clinics all over the world.[9] However, there are still very few centers that have implemented EWS technology to this point all around the world including India.

The mix-up event can leave embryologists and IVF clinics to face legal challenges and regulatory sanctions. Embryologists working without witnessing the system are prone to increase mismatching risks during the IVF process and a mix-up could also potentially damage the reputation of the clinic and subsequently lose the confidence of any prospective patients coming for infertility treatment. The common practice of the manual double witness approach is also vulnerable to human errors may be due to check omission, involuntary automaticity, check incomplete, and handling of multiple gametes at the same time.[10] The main objective of the study was the validation and integration of an electronic witnessing system for patient care in a busy IVF clinic in India and its efficacy on lab performance. EWS system uses radio frequencies to identify the RFID tags; these radio frequencies are claimed to be safe for human gametes and embryos, however for the safety of our patients, we checked the effect of radiofrequency on the gametes and embryos by comparing fertilization rate, cleavage rate, good embryo formation, and pregnancy rate. We further assessed the satisfaction index of clinicians, clinical embryologists, and staff personnel working at the center for their concerns about possible biological mix-up gamete after the installation of electronic witnessing.

Materials and Methods

The study period includes retrospective analysis of all treatment cycles done through EWS for validation and postvalidation in a clinical setting from August 2019 to January 2020 at a single private infertility clinic. We analyzed a total of 187 consecutive infertile patients for installation and validation of EWS with an average of 6–8 cases/day over 6 months. The institutional review board of the Medicover Fertility approved the study vide letter no. *MCRM*/01/2020, and signed informed consent was obtained from all patients. The laboratory outcomes were analyzed for maturation rate, fertilization rate, cleavage rate, and development of good-quality embryos and further followed up with pregnancy rate for risk assessment of electromagnetic radiation on outcomes in the clinical setting. The data points were analyzed by comparing with EWS group with additional groups defined as follows; Group 1: control group with patient gametes (embryos/sperms) that were not exposed to any form of EWS; Group 2: positive control group where gametes were exposed to only EWS without RFID tags; and Group 3: EWS group where gametes were exposed to both EWS and RFID tags on dishes and tubes).

All patients were informed about the use of EWS on the day of oocyte retrieval and were given an individual electronic ID card by the registration team to verify and identity the patient that matches eggs, sperm, and embryos all procedural steps. The EWS was installed at the clinic procured from RI-Witness™ (Research Instrument, Cooper Surgical, Denmark) with self-adhesive RFID microchips (tags) and RFID reader. The IVF workstations were also installed with RFID tag readers and touch screens to detect tagged culture dishes while performing procedural steps within its range. There was a visual and audible alarm by the EWS if a sample mismatch occurs in the working area and the same information was saved by the system for each patient. After installation of hardware and software in the working area, self-adhesive RFID tags were attached to all the laboratory plastic wares for its detection by readers. While working on RFID tagged culture wares, patient's identity was monitored for all the critical stages of the treatment cycle with simultaneous capture of cycle progression and embryologist action during the entire cycle.

A well-defined workflow chart was prepared as per the defined process followed at the laboratory as shown in Figure 1 and only compatible samples were taken forward as per the IVF process working one at a time. The IVF witness system monitors every instance when gametes or embryos are transferred from one tube or dish to the next to ensure that only one patient is worked at a time. EWS was constantly monitoring all steps as per defined workflow so that an identity check can never be overlooked. The outcomes were analyzed for mismatches under the following category as mismatches: a mismatching event occurs in the medical process when patients are not correctly linked with their specimens or specified treatments. The categories of mismatches that were analyzed included *Use*/*Proximity (U)*: defined as errors due to the presence of tags outside of the workstation inappropriately pre-assigned identities because of their proximity to the workstation or identified as secondary mismatches derived from acceptable common errors, that is, pre-allocated tags within the frequency range of the reader, but outside of the workstation. *True (T)*: Mismatches that are identified due to the presence of tagged culture-ware (dishes and/or tubes) from two different patients in the treatment area co-located in the same workstation (discarded or empty dishes present in work area poses a potential risk of misidentification as patient sample).

The safety of the EWS was studied by looking at clinical pregnancy rates. Maturation, fertilization and cleavage rate, and embryo development rate of good-quality day 3/day 5 embryos between the groups were observed and analyzed. Satisfaction assessment was done by taking feedback by filling a questionnaire designed to record the satisfaction level of treating clinicians, clinical embryologists and staff personnel working in the laboratory to assess their perspective on the advantages of having such a system after installation. The questionnaire comprises five questions for the clinician, clinical embryologist and staff, and answers to each were linked on to the Likert scale values ranging from 1 to 5. The values corresponded to either categorical variable (1 = no, never; 2 = rarely; 3 = sometimes; 4 = frequently; 5 = always; 6 = no viewpoint) [Table 1]. As an outcome, the total integration and installation time of an electronic witnessing system in the working area along with setting and configuration of the working flowchart for witness points and training time for all the clinical embryologists was evaluated.

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD. Quantitative variables were compared using ANOVA and Qualitative variables were compared using Chi-Square test. Univariate and multivariate logistic and linear regression was used to find out the effect of groups on outcome. A P value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) IBM

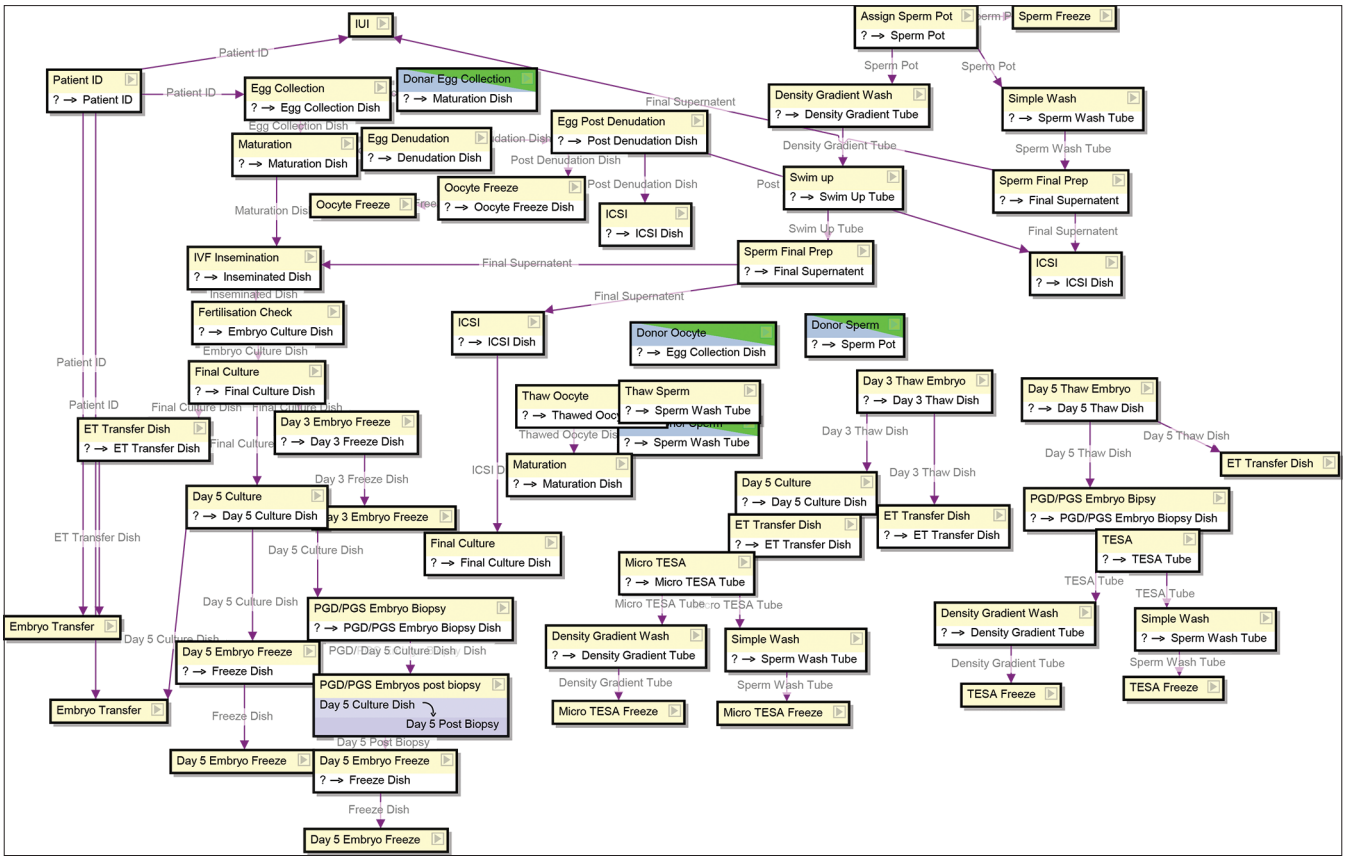
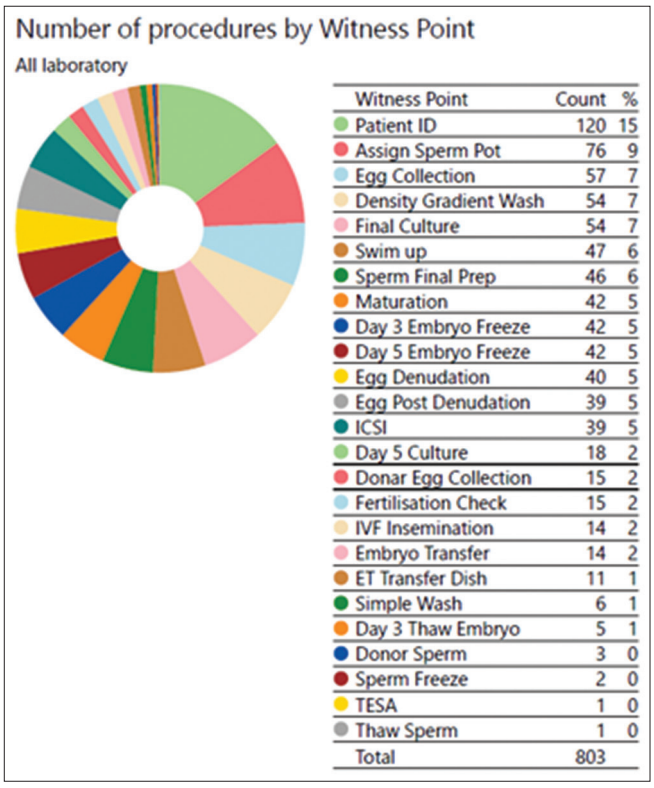


Figure 1: Elaborate workflow chart as all defined *in vitro* fertilization procedures followed in the laboratory table corrections

Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.00, IBM, Armonk, NY, United States of America.

Results

During the study, a total of 187 patients were analyzed involving 128 IVF cycles with 803 electronic witnessing steps allocated as per the assigned procedure per location. A total of 751 RFIG tags were utilized in 77 patients assigned barcodes for all the analyzed cycles. In total 21 red flags were highlighted by the EWS. All the flagged mismatches by EWS were from pre-allocated tags from the different patients within the frequency range of the EWS reader. Out of total highlighted flags, 12 were labeled as *Use/Proximity (U)* due to the presence of discarded dish, pre-allocated tags within the frequency range of the reader, and 07 due to the deliberate introduction of tags during trial runs assigned by admin. During validation of EWS, a total of 02 (0.46%) red flags were highlighted by EWS that could be designated as *True (T)* mismatches due to the introduction of pre-allocated samples from two different patients in the work area [Table 2]. During the entire validation procedure and after installation of EWS in the clinical setting a manual double witnessing system was also simultaneously in place for each IVF procedural



Witness Point	Count	%
Patient ID	120	15
Assign Sperm Pot	76	9
Egg Collection	57	7
Density Gradient Wash	54	7
Final Culture	54	7
Swim up	47	6
Sperm Final Prep	46	6
Maturation	42	5
Day 3 Embryo Freeze	42	5
Day 5 Embryo Freeze	42	5
Egg Denudation	40	5
Egg Post Denudation	39	5
ICSI	39	5
Day 5 Culture	18	2
Donar Egg Collection	15	2
Fertilisation Check	15	2
IVF Insemination	14	2
Embryo Transfer	14	2
ET Transfer Dish	11	1
Simple Wash	6	1
Day 3 Thaw Embryo	5	1
Donor Sperm	3	0
Sperm Freeze	2	0
TESA	1	0
Thaw Sperm	1	0
Total	803	

Figure 2: Pie chart with details of electronic witness system analytics of *in vitro* fertilization process done as per witness point according to defined workflow

step along-side EWS. In the entire study, there were zero errors or mismatches that could be designated as reported as human errors.

Table 1: Questionnnaire to assess the satisfaction level of clinician, clinical embryologist, and staff working at the center before and after installation of electronic witness system

Serial number	Question	Electronic witnessing system
1	With the implementation of witnessing system, the possibility of human error in minimized, due you think it is going to help in your patient counseling and satisfaction?	
2	Since witnessing system can track each step of gamete manipulation in the IVF laboratory. How much do you think it can contribute to the success rates of your ART treatment?	
3	Now that you are aware of witness system, does it increase your preference or trust in an IVF center as a professional (consultant/ embryologist) that have implemented this technological innovation?	
4	The witnessing system helps to identify if there is a sample mix up or another patient sample. Given this advantage in the process, how much confidence do you have in system?	
5	Since witnessing system track and check every step of sample manipulation in the IVF laboratory and hence there is extremely low possibility of omission of procedural steps. Does the implementation of such a system provide peace of mind to as a professional (consultant/ embryologist)?	

Score: 0=No viewpoint, 1=Not at all, 2=A little, 3=Moderately, 4=A lot, 5=Extremely. IVF=*In vitro* fertilization, ART=Assisted reproduction technology

Table 2: Summary of witness points and patient included in the study

Measurement	Value
Number of tags used	751
Number of witness points	803
Number of patients seen	187
Number of cycle	128
Number of barcodes	77
Number of discards	415
Number of mismatches	21
Number of admin assign	7
Use/proximity (U) mismatches	12
True mismatches (T)	2
Mismatch identified by manual double witnessing	2

As per EWS analytic, the number of procedures as per location was analyzed with the maximum number of witnessing steps completed at the registration desk 188 (23%) followed by while performing ICSI, 188 (23%), and 162 (20%) during semen sample processing captured through sperm reader. There were 137 (16%) witness steps at the time of ovum pick-up followed by ET and 131 (16%) witnessing steps at the cryo-workstation during cryopreservation of embryos [Figure 2]. The further analysis number of procedures done per witness revealed maximum at the time of registration while assigning patient ID 120 (15%) followed by assigning sperm port 76 (09%), egg collection 57 (7%). Further witnessing included egg denudation 40 (5%), egg post-denudation 39 (5%), maturation 42 (5%), ICSI 39 (5%), IVF insemination 14 (2%), density gradient wash 54 (7%), swim-up 47 (6%), sperm final preparation 46 (6%), final culture 54 (7%), day 5 embryo freezing 42 (5%), and day 3 embryo freezing 42 (5%), as shown in Figure 3.

Table 3 further depicts data on secondary outcomes to evaluate the efficacy and safety concern of EWS on maturation, fertilization, cleavage rate, and embryo development rate of good-quality day 3/ day 5 embryos between the groups. In the EWS group, the maturation rate (83.1%), fertilization rate (74.3%), cleavage rate (93.5%), day 3 Grade A embryo development rate (64.6%), and good grade blastocyst development rate (26.4%) were observed that was comparable to other groups with no significant difference ($P > 0.005$). A further follow-up of frozen ET including both day 3 and day 5 cycles of EWS cases resulted in a clinical pregnancy rate (50.0%) that was higher than other groups [Table 4]. The results were statistically not significant as the sample size was small.

An average of 12–15 RFID tags was used per IVF/ICSI cycle yielding an additional cost of approximately 500–

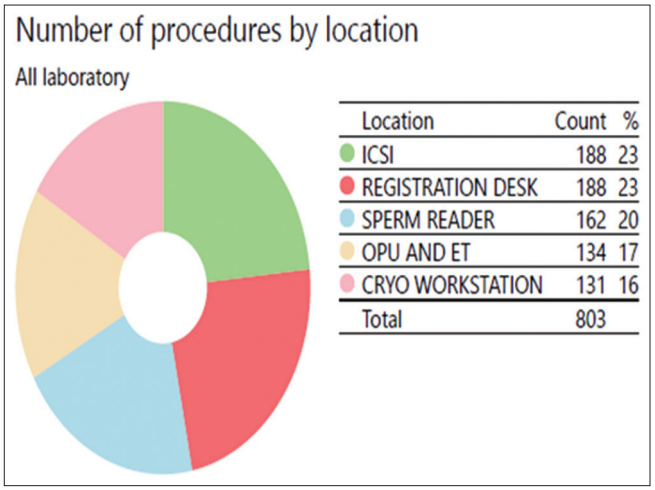


Figure 3: Details of number of procedures done per location

Table 3: Data on secondary outcomes to evaluate the efficacy and safety of electronic witness system for maturation rate, fertilization rate, and cleavage rate followed formation of good quality day 3 embryo development rate and day 5 blastocyst development rate (day 5) compared to control groups

Groups/cases (*n*)	Number. of OCC retrieved	OCC/ patient	Maturation rate (%)	Fertilization rate (%)	Cleavage rate (%)	Day-3 (Grade A) embryo development rate (%)	Day 5, blastocyst good-grade development rate (%)
Control (185)	2263	12.23	86.04	75.60	100	60.73	28.60
Positive control (408)	5309	13.01	75.87	76.32	99.61	59.11	22.17
EWS (56)	695	12.41	83.16	74.39	93.95	64.60	26.48

EWS=Electronic witness system

Table 4: Clinical pregnancy data of frozen embryo transfer cycles including of both day 3 and day 5 embryos in electronic witness cases in comparison to other groups

FET (*n*)	Number of embryos thawed	Embryo survival rate (%)	Implantation rate (%) Sac/embryo	Biochemical pregnancy rate (%)	Ongoing pregnancy rate (%)
Control (346)	846	98.46	20.85	44.8	41.04
Positive control (536)	1364	96.92	22.94	48.88	44.78
EWS (14)	30	100	23.33	57.14	50

EWS=Electronic witness system, FET=Frozen embryo transfer

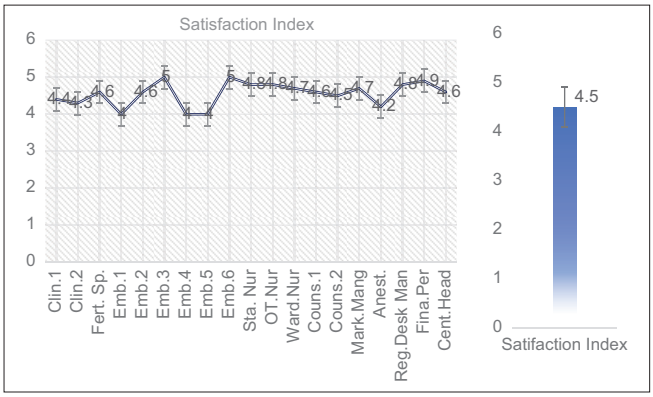


Figure 4: Satisfaction graph of clinician, clinical embryologist, and staff personnel working at the center after installation of electronic witness system along with mean satisfaction index after installation of electronic witness system (4.5 ± 0.31)

700 INR/patient cycle. This cost was minimal considering the overall advantages and benefits for the patient. The total time taken for the installation and integration for the EWS system was 7 working days and another 1 week for imparting training to doctors, clinical embryologists, operating theater nurse, and staff personnel working on the registration desk. The average satisfaction index of the clinician, clinical embryologist, and staff recorded was found to be 4.5 ± 0.31 SD after the installation of EWS in the current workflow at our center [Figure 4].

Discussion

EWS was introduced at our center with attention focused on reducing the possible errors with standardization and traceability, thus making all IVF procedures safer.[2,8] During the validation studies, EWS accurately records all the applicable laboratory procedures and identified zero-mismatches that could be designated as *True (T)* errors. Because there were no true errors it compares favorably with already published error rates of < 1% for IVF related laboratory activities.[3,7,10] There were only 02 (0.46%) highlighted cases flagged by EWS that can be designated as *Use/Proximity (U)* mismatches due to pre-allocated samples in the workstation area during the installation and validation process.

In a busy tertiary infertility clinic setting, EWS will help decrease the risk of human error every time samples are moved from one tube or dish to another and thus safeguarding every step of the IVF procedure. It identifies patient gametes and is monitored at every stage of the assisted reproductive technology (ART) cycle.[6,8] There have been animal and cell lines studies that show a low level of radiofrequency are safe, but still, further scientific evidence is required for the systematic use of such electronic devices in the IVF laboratory and might interfere somehow with the biology of gametes and embryos.[11,12] However, other than using very moderate radio frequencies, the exposition time is limited to only a few seconds required during some steps of cell manipulation outside the incubators.[13-15] A lot of research papers reported that exposure to electromagnetic waves used in this system might alter the reproductive endocrine hormones, embryonic development, and fetal development. However, these effects vary and differ according to the frequency, exposure time, and strength of the electromagnetic waves. In our study, the EWS test group has shown better embryo formation and pregnancy rates compared to the control and control group. These data help us to evaluate that radiofrequencies used in EWS are not affecting gametes and embryos adversely. Therefore, a careful approach is required to assess

the effect of these radiofrequencies used in EWS on epigenetic and *in utero* development of a fetus. There are no studies done with sufficiently long durations to ensure that there are no effects of electromagnetic waves.[14,16] The first concern about the RFID tags is that they can't be currently recycled and thus potentially may cause environmental hazard. Second, tags utilized in the IVF cycle are expensive and their long-term usage may have huge financial implications for both patients and infertility clinics.[5,10,11] Therefore, further efforts should be undertaken to make cost-effective and biodegradable tags so that more and more patients can be benefitted and clinics start implementing into the routine practice.[6,8]

EWS give complete peace of mind to embryologist while performing all the critical IVF steps in a busy IVF laboratory. The mismatch of human gametes can stake the reputation of the clinic by failure to identify true mismatch that could lead to a catastrophic effect. Because electronic witness tracks each step of gamete manipulation, thus an IVF laboratory that has installed EWS the overall success rate of the clinic might increase, however further studies are required to test this hypothesis. As EWS help in reducing the risk for sample mix up in IVF cycles, it has proved to be a trusted strategy from the patient perspective. There are have been few studies that have also evaluated for patient satisfaction level and have concluded that patients gained further confidence at the centers that have implemented EWS during their course of the treatment cycle.[13]

Conclusions

In our initial experience, EWS has enormous potential to prevent the biological mismatch of gametes. EWS checks and tracks every step as per defined standard operating protocol and helps reducing stress related to gamete mismatch to clinicians, embryologists, and the patient during the entire cycle. Moreover, the warning of mismatches allows for immediate corrective intervention and safeguarding the reliability of all the IVF process. The benefit of EWS includes traceability of each step performed, reduction of staff workload, distractions, and overall increased satisfaction level and peace of mind to the embryologist. EWS installed into our workflow increased the satisfaction and confidence of clinicians and embryologists during every step of the cycle. Our preliminary data also show that EWS does not affect the gametes, embryos, and pregnancy rate adversely, however a well-designed larger randomized clinical trials should be undertaken to evaluate the efficacy and safety of EWS on human gametes.

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Conflicts of interest

There are no conflicts of interest.

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