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IVF laboratory management through workflow-based RFID tag witnessing and real-time information entry

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Abstract

Background Dual-person inspection in IVF laboratories cannot fully avoid mix-ups or embryo transfer errors, and data transcription or entry is time-consuming and redundant, often leading to delays in completing medical records.

Methods This study introduced a workflow-based RFID tag witnessing and real-time information entry platform for addressing these challenges. To assess its potential in reducing mix-ups, we conducted a simulation experiment in semen preparation to analyze its error correction rate. Additionally, we evaluated its impact on work efficiency, specifically in operation and data entry. Furthermore, we compared the cycle costs between paper labels and RFID tags. Finally, we retrospectively analyzed clinical outcomes of 20,424 oocyte retrieval cycles and 15,785 frozen embryo transfer cycles, which were divided into paper label and RFID tag groups.

Results The study revealed that comparing to paper labels, RFID tag witnessing corrected 100% of tag errors, didn't affect gamete/embryo operations, and notably shorten the time of entering data, but the cycle cost of RFID tags was significantly higher. However, no significant differences were observed in fertilization, embryo quality, blastocyst rates, clinical pregnancy, and live birth rates between two groups.

Conclusions RFID tag witnessing doesn't negatively impact gamete/embryo operation, embryo quality and pregnancy outcomes, but it potentially reduces the risk of mix-ups or errors. Despite highly increased cost, integrating RFID tag witnessing with real-time information entry can remarkably decrease the data entry time, substantially improving the work efficiency. This workflow-based management platform also enhances operational safety, ensures medical informational integrity, and boosts embryologist's confidence.

Keywords IVF laboratory, Safety, RFID tag, Workflow-based management, Real-time information entry

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Background

Assisted Reproductive Technology (ART) is a valuable tool for treating infertility in couples who desire to have children. However, it is important to note that ART differs from other medical fields in that the risk of medical errors occurring is relatively low. While the majority of patients who require ART treatment do not have major illnesses, the ultimate goal of their treatment is to have healthy biological offspring. Despite this, the consequences of medical errors during ART can be severe, such as gamete or embryo mix-ups or errors during embryo transfer, resulting in the birth of biological offspring that do not belong to the patients [1], which can have devastating effects on patients and their families.

To date, there have been relatively few studies conducted on medical errors occurring during ART treatments thus far. The Boston IVF center at Harvard Medical School in the United States found that, based on a 10-year analysis of medical adverse event data, 0.92% of patients were affected by medical errors during ART treatment cycles [2]. ART risk events include clinical nursing risk events (accounting for about one-third), IVF laboratory medical risk events (accounting for about one-third), information management risk events (accounting for about one-third), and other risk events [3]. Compared with clinical and nursing aspects, the complexity and technical aspects involved in human IVF laboratories increase the likelihood of medical risk events occurring. As previously mentioned, the impact of such errors in IVF laboratories is particularly severe.

Therefore, it is crucial that practitioners involved in assisted reproductive technology (ART) undergo comprehensive training and adhere to strict protocols to prevent the occurrence of errors. This can considerably reduce the risk of medical errors in ART, enabling patients to receive optimal care and successfully realize their desire for healthy biological offspring. Many ART organizations, such as the European Society for Human Reproduction and Embryology (ESHRE), Federacion Latinoamericana de Sociedades de Esterilidady Fertilidad (FLASEF), Human Fertilisation and Embryology Authority (HFEA), and China Society of Reproductive Medicine (CSRM), have published multiple versions of guidelines to prevent the occurrence of medical errors during ART [4–7]. All of these guidelines impose strict requirements on practitioners to ensure accurate identification of patient identity information and all surgical materials they utilize. Furthermore, they enforce rigorous "double witness" by at least two persons throughout the operation process [8]. Even so, it remains challenging to completely eliminate the possibility of mix-ups or errors. Consequently, the electronic witnessing systems (EWS), utilizing barcode and radio frequency identification (RFID) tags as primary information carriers, have been developed to prevent mix-ups or mistakes during ART [9–11].

Additionally, clinical embryologists are required to transcribe and enter a substantial amount of patient data for regulatory reporting and to support evidence-based practice. This process typically involves multiple electronic or paper records, which often leads to duplicated information entry. Unfortunately, data entry is often perceived as a low priority task by staff, resulting in delays. Moreover, the responsibility for different steps in the process is often assigned to specific individuals, which can cause workflow disruptions in cases of absence or part-time work [12]. Consequently, data entry is frequently completed in batches, leading to significant delays.

To tackle these challenges, a workflow-based management platform was installed on each workstation in our IVF lab, which incorporated an electronic management system for ensuring patient identification and real-time input of their medical information during surgical and laboratory procedures. In this study, we initially analyzed the error correction capability of the system through a simulated semen preparation experiment. Subsequently, we assessed its impact on work efficiency, focusing specifically on the time required for operation and data entry. Furthermore, we conducted a comparison of the cycle costs associated with paper labels and RFID tags. Finally, we also conducted a retrospective analysis of IVF laboratory and clinical outcomes from July 2014 to June 2022 and compared the data before and after the adoption of the RFID tag witnessing platform, aiming to determine if there were any potential negative effects on laboratory and clinical outcomes due to the implementation of this new platform.

Materials and methods

Muti-module IVF laboratory management system

The routine operations of IVF laboratory involve multiple tasks, including patient identification witnessing, gamete and embryo manipulation, data entry and management, and information exchange with the clinical management platforms.

The IVF laboratory management system in our center of reproductive medicine consists of seven major modules arranged in a specific order: oocyte retrieval, semen preparation, IVF or intracytoplasmic sperm injection (ICSI), embryo observation, embryo cryopreservation, embryo thawing, and embryo transfer (Fig. 1A). Additionally, embryologists are responsible for witnessing patient identification, recording and entering data, and completing medical records related to embryo laboratory procedures.

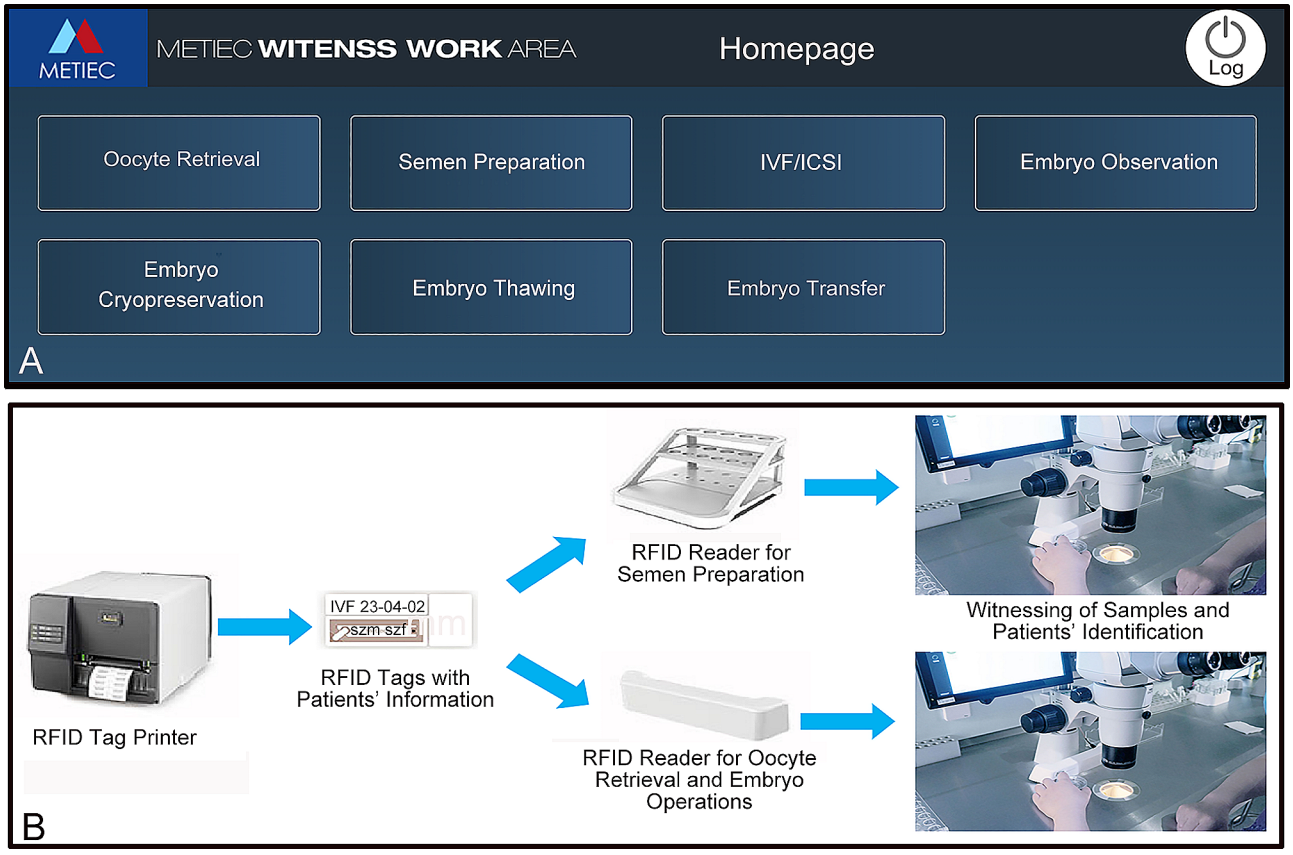

Fig. 1 Homepage of Electronic Witnessing System and the Witnessing Procedure through RIFD tags. (**A**) This homepage covers all the operational processes of an IVF laboratory, which includes oocyte retrieval, semen preparation, IVF, ICSI, embryo observation and grading, embryo cryopreservation and thawing, and embryo transfer. (**B**) RFID tags are printed and used to authenticate the various procedures involved in semen preparation, oocyte retrieval, and embryo operations throughout the entire IVF process. RFID, Radio frequency identification

Acquisition of patients' information and printing of RFID tags

The patients' basic medical information, including names, medical record numbers (MRN), identification (ID) numbers, and photos, was pre-entered into the electronic medical record (EMR) management system. These data are associated to RFID tag printing platform, creating an identification database. On the day prior to scheduled surgeries, RFID tags (as shown in Fig. 1B) are printed and securely attached to IVF lab consumables, including semen collection containers, test tubes, and culture dishes according to the EMR numbers and patients' names. These RFID tags store the ID information readable by electronic reader and also print the visible information like patient names, medical record numbers, and surgery dates on surface. They are utilized for witnessing patients' ID during gamete and embryo operation, or medium changeover, ensuring consistency not only between patients and lab items, but also among different lab items of same patient.

Woking mode of workflow-based IVF laboratory management system

The all-in-one computer with a pre-installed RFID tag witnessing and management system was equipped to perform information witnessing and real-time data entry tasks on each workstation (operation point). The operation modules based on procedural workflow at workstation carry out patient identification witnessing and data entry while complete the related laboratory operations (Fig. 2 and Supplementary File 1).

At first, the embryologists and supervisors log in operation modules using personal accounts and passwords (Fig. 2). Once an operation module is accessed, the patient list will automatically appear on the left side of the screen. After the RFID reader is switched on, the embryologists witness the patient identification by a RFID tag. Once the witnessing is successful, the system broadcasts the couple's name and the patient undergoing operation is automatically highlighted in pink (notes: if it doesn't match, the system will emit a beeping alarm). Meanwhile, the interface displays a recordable status (in the middle-interface of Fig. 2), indicating that the operation can be

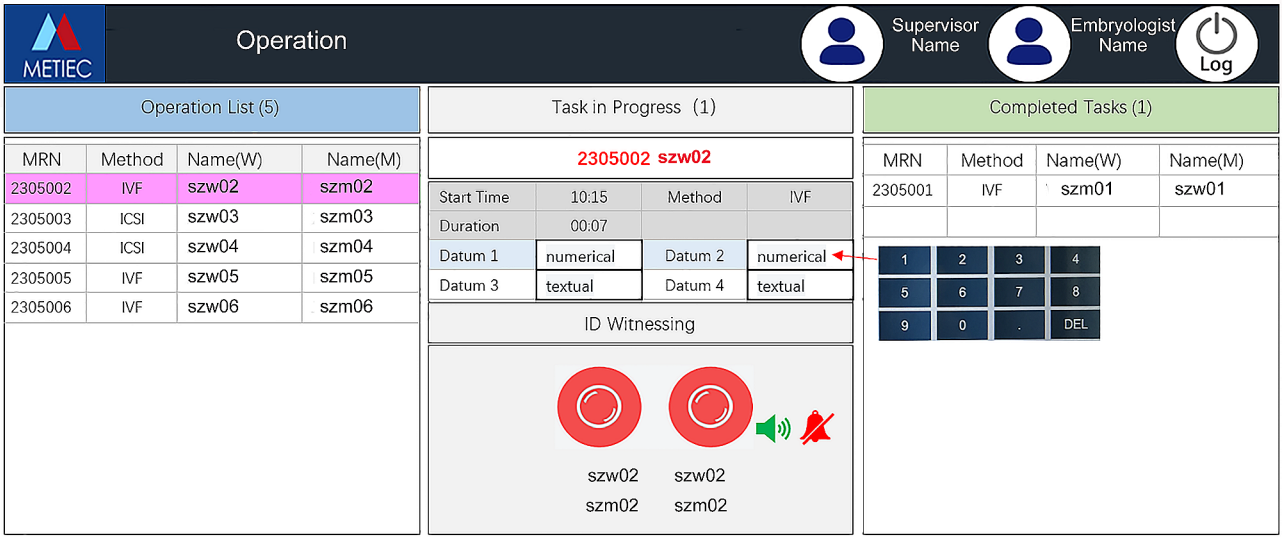

Fig. 2 Working Model of RFID Identification Witnessing and Data Entry Based on Workflow in IVF Laboratory The procedural workflow-based operation modules at each workstation are responsible for patient identification verification and data entry, as well as completing related laboratory operations. Once embryologists log in to the operation modules using their personal accounts and passwords (located in the top right corner), they can access the operation module, and the patient list will appear on the left side of the screen. Once the RFID reader is activated and the verification process is passed, the system displays the couple's name, and the patient undergoing the operation is highlighted in pink (located in the left interface). Additionally, the middle interface displays the recordable status. The embryologists can input gamete or embryo data, but all textual data must be selected from a drop-down menu, while numerical data can be directly entered (using the blue numerical box located in the right interface). After the operation for one couple is completed, the list of patients who have finished will be displayed in the completed task list (located in the right interface)

processed. During the operation, the system automatically records the start time.

In the middle-interface of operation module, the embryologists can real-time input the data on gametes or embryos like the amount and quality of oocytes, the status of semen before and after preparation, and the status of embryos for culture, cryopreservation, thawing and transfer. However, there are subtle differences among different operations such as oocyte retrieval (Supplementary Fig. 1), semen preparation (Supplementary Fig. 2), IVF (Supplementary Fig. 3) or ICSI (Supplementary Fig. 4), zygote denudation (Supplementary Fig. 5), embryo observation and grading (Supplementary Fig. 6), embryo cryopreservation (Supplementary Fig. 7), embryo thawing (Supplementary Fig. 8), and embryo transfer (Supplementary Fig. 9). All textual data must be selectively pushed through a dropdown menu, while numerical data could be entered by direct input (Fig. 2). Furthermore, it is crucial to conduct the data entry process under the supervision of a supervisor to guarantee the accuracy of all gametes or embryos data. Finally, the data is promptly pushed to the EMR management system by clicking the data pushing button.

Once the operation is completed, the list of patients who have finished will be automatically displayed in the completed task list on the right side.

Simulation experiment for testing error correction rates of RFID tag witnessing

The error correction rate of RFID tags is a critical factor that determines the accuracy and reliability of their data transmission and reception capabilities. A higher error correction rate indicates a more reliable and precise RFID tag system. Therefore, we conducted a simulated experiment in semen preparation to test the instant error correction rates when using mixed labels or tags with similar names.

During the simulated semen preparation process, RFID tags were printed and pre-affixed to semen collection containers and test tubes. The purpose was to evaluate whether the personnel are able to detect mixed errors in situations where similar names are mistakenly assigned. During witnessing process, the operation embryologists except for the experiment supervisor are not informed that approximately 5% of the tags have been randomly replaced with similar tags (where one of three identical tags is replaced with a tag featuring a similar patient's name). While one embryologist performs the witnessing, the supervisor conducts a thorough supervision within a short time to identify any issues that may arise and calculate the error correction rates. The traditional paper labels are used as the control in this experiment. The error detection rates were calculated by dividing the number of errors correctly detected by the total number of mixed error label/tags.

Comparison of operation time between paper label and RFID tag witnessing system

We conducted a study to compare the efficiency of gamete and embryo operations using paper labels and RFID tags. Throughout the operational process, the RFID tag witnessing system automatically records the time taken for each procedure, including oocyte retrieval, semen preparation, IVF, zygote denudation, oocyte denudation and ICSI, embryo observation, embryo cryopreservation, embryo thawing, and embryo transfer. On the other hand, for paper label verification, embryologists manually record the time of each procedure. To assess the impact of using RFID tags versus paper labels, we compared the recorded operational time for each procedure. Mean values and their respective standard deviations (SD) are presented for all time measurements, whether in minutes or seconds, to ensure accuracy and facilitate statistical analysis.

Comparison of time taken for information entry or transcription between paper label and RFID tag witnessing system

RFID tag witnessing system automatically records the time of data entry and information pushing during oocyte retrieval, semen preparation, IVF, ICSI, embryo observation, embryo cryopreservation, embryo thawing, and embryo transfer. On the other hand, the time for transcribing paper record and data entry to EMR system was required record manually. To assess the impact of using RFID tags versus paper labels, we analyzed the recorded time of information entry or transcription for each procedure. All the time were presented as mean values and respective standard deviations to facilitate statistical analysis.

Amount and cost of paper labels and RFID tags for each IVF cycle

The average number of paper labels and RFID tags used per IVF cycle was calculated, and their respective costs for each cycle were converted into US dollars. These values are presented as mean values along with their corresponding standard deviations to ensure accurate representation and facilitate analysis.

Patients

This retrospective study included 20,424 patients who underwent IVF/ICSI treatment between June 2014 and June 2022. Of these patients, 13,390 were in the paper label group and 7034 were in the RFID tag witness group. Inclusion criteria were patients aged 20 to 53 years undergoing IVF/ICSI treatment with a minimum of two follicles (>18 mm) in the oocyte collection procedure. Paper labels were used from June 2014 to September 2019, and RFID tag witness and management system was launched from October 2019 to June 2022. All patients received pharmacologic ovarian stimulation for ART and were diagnosed with infertility related to female factor, male factor, dual factors, and unexplained infertility. Data analysis of patient medical records in this study was performed in accordance with the Declaration of Helsinki and was approved by the ethics committee of Guangdong Second Provincial General Hospital (No. 2023-KY-KZ-179). The need for written informed consent to participate was waived by the ethics committee Guangdong Second Provincial General Hospital due to retrospective nature of the study.

Clinical outcomes of paper labels and RFID tag witnessing

To assess the effectiveness of the RFID tag witness system, we conducted a clinical retrospective analysis to evaluate its impact on clinical treatment. Patients were divided into two groups based on the time period of operation: the control group, which utilized the traditional paper label system, and the group using the RFID tag witness and management system. We compared various parameters between the two groups, including the average number of oocytes per cycle, rates of normal fertilization, usable embryos, high-quality embryos on Day 3, and blastocyst formation.

Additionally, to determine if the RFID tag witness system had any impact on embryo transfer, we also analyzed the average number of transferred embryos, female ages, implantation rate, clinical pregnancy rate, and live birth rate following fresh or frozen embryo transfer.

Statistical analysis

The $\chi 2$ test was utilized to analyze data related to the percentages of infertility factors, as well as rates of fertilization, embryo development, pregnancy, and live birth. In addition, the unpaired two-tailed t test was employed to compare average values such as maternal patient age, number of embryos, time and cost. Statistical significance was indicated by p-values < 0.05.

Results

Instant error correction rates during simulated paper label and RFID tag witnessing

The results of the study revealed that when confronted with intentionally disrupted 504 paper labels, the embryologist was able to identify only 22 errors from 25 error labels through visual inspection, resulting in an error correction rate of $88.67 \pm 10.43\%$. However, when faced with intentionally 528 mixed RFID tags, the embryologist was able to instantly detect all 27 errors by relying on RFID tag witnessing, resulting in a 100% error correction rate. This finding suggests that compared to visual inspection of paper labels, RFID tag witnessing can effectively prevent errors in recognizing similar names and significantly

enhance the security and reliability of RFID tag witnessing ($P=0.0413$; Fig. 3; Supplementary Table 1).

Effects of paper label and RFID tag witnessing on gamete or embryo operation time

The results, as shown in Fig. 4 (Supplementary Table 2), demonstrated that the time between paper labels and RFID tags for collecting each oocyte (Fig. 4A), preparing semen (Fig. 4B), performing IVF (Fig. 4C), denuding each zygote (Fig. 4D), denuding each COC for ICSI (Fig. 4E), performing ICSI on each MII oocyte (Fig. 4F), observing each embryo (Fig. 4G), freezing embryo(s) per cryovial (Fig. 4H), thawing embryo (Fig. 4I), and transferring embryo(s) (Fig. 4J) were 1.12±0.31 vs. 1.06±0.15 min ($P>0.05$), 20.06±0.62 vs. 19.91±0.38 min ($P>0.05$), 4.5±0.68 vs. 4.63±0.77 s ($P>0.05$), 0.5±0.11 vs. 0.51±0.09 min ($P>0.05$), 0.54±0.22 vs. 0.52±0.18 min ($P>0.05$), 0.95±0.11 vs. 0.98±0.06 min($P>0.05$), 4.52±0.9 vs. 4.47±0.54 s ($P>0.05$), 7.36±1.06 vs. 7.55±0.31 min ($P>0.05$), 13.82±0.51 vs. 14.02±0.47 min ($P>0.05$), and 3.59±0.47 vs. 3.6±0.43 min ($P>0.05$), respectively. These findings indicate that the use of RFID tag witnessing platform did not significantly impact the duration of these operations, including oocyte retrieval, semen preparation, IVF, oocyte or zygote denudation, ICSI, embryo observation, embryo cryopreservation, embryo thawing and embryo transfer.

Difference on the time of data transcription and entry between paper label and RFID tag witnessing

The results in Fig. 5 (Supplementary Table 3) showed that the time of transcription and/or data entry between paper labels and RFID tag witnessing platform for oocyte retrieval (Fig. 5A), semen preparation (Fig. 5B), IVF (Fig. 5C), ICSI (Fig. 5D), embryo observation (Fig. 5E), embryo cryopreservation (Fig. 5F), embryo thawing (Fig. 5G) and embryo transfer (Fig. 5H) were 31.00±6.98 vs. 6.75±1.71 s ($P=0.0005$), 88.7±12.55 vs. 17.25±1.71 s ($P<0.0001$), 26.25±2.63 vs. 7.25±2.22 s ($P<0.0001$), 96.75±6.60 vs. 31.75±2.36 s ($P<0.0001$), 74.50±7.59 vs.

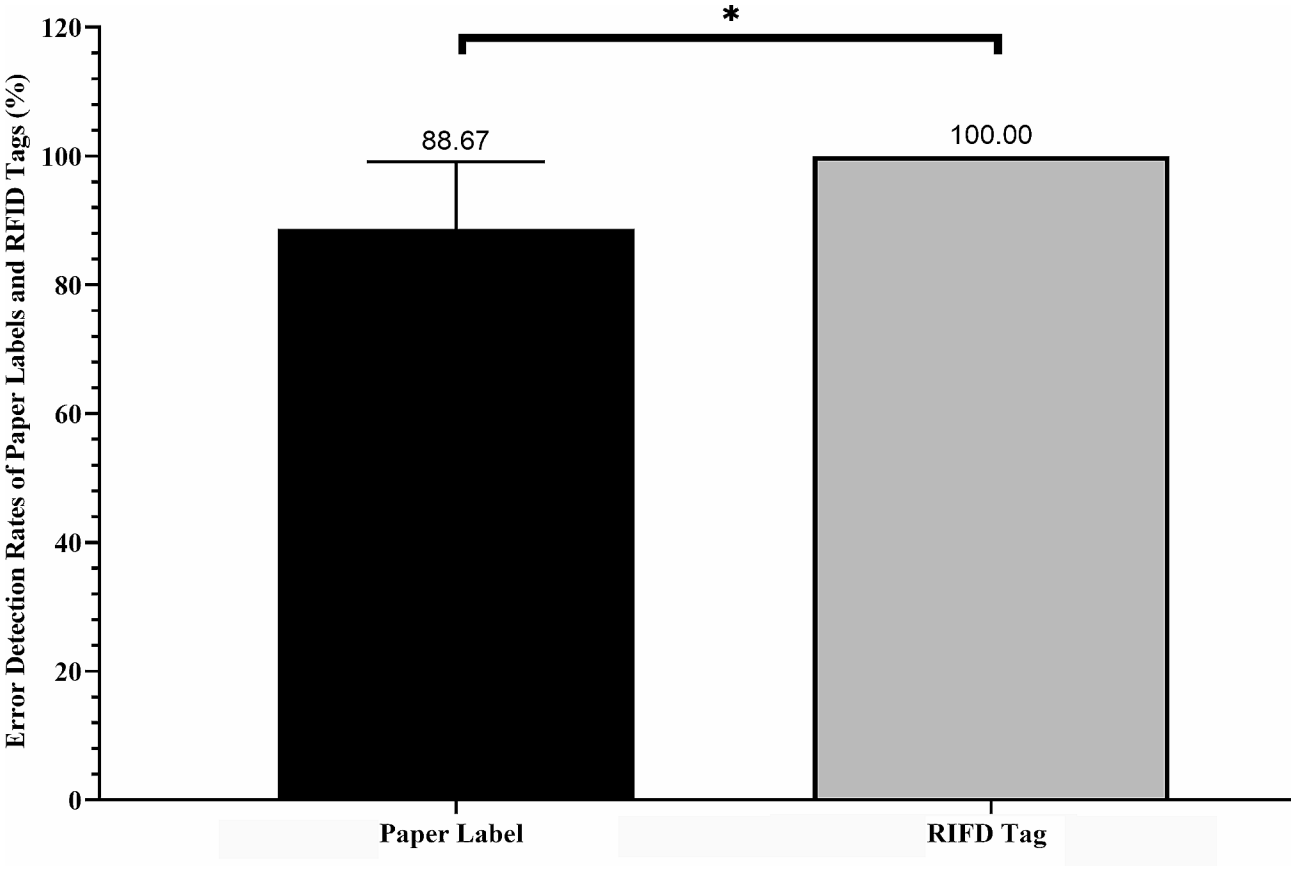

Fig. 3 Error Correction Rates During Simulated Paper Label and RFID Tag Witnessing. The error detection rates were calculated by dividing the number of errors correctly detected by the total number of mixed error label/tags, and expressed as the mean ± standard deviation (SD). In the case of intentionally disrupted paper labels, the embryologist was able to identify 22 out of 25 error labels through visual inspection, resulting in an error correction rate of 88.67 ± 10.43%. However, when faced with intentionally mixed RFID tags, the embryologist was able to instantly detect all 27 errors by relying on RFID tag witnessing, achieving a 100% error correction rate. An unpaired t test was used to compare the values between the paper label and RFID tag groups, and the "*" symbol on the bar graph indicates a significant difference

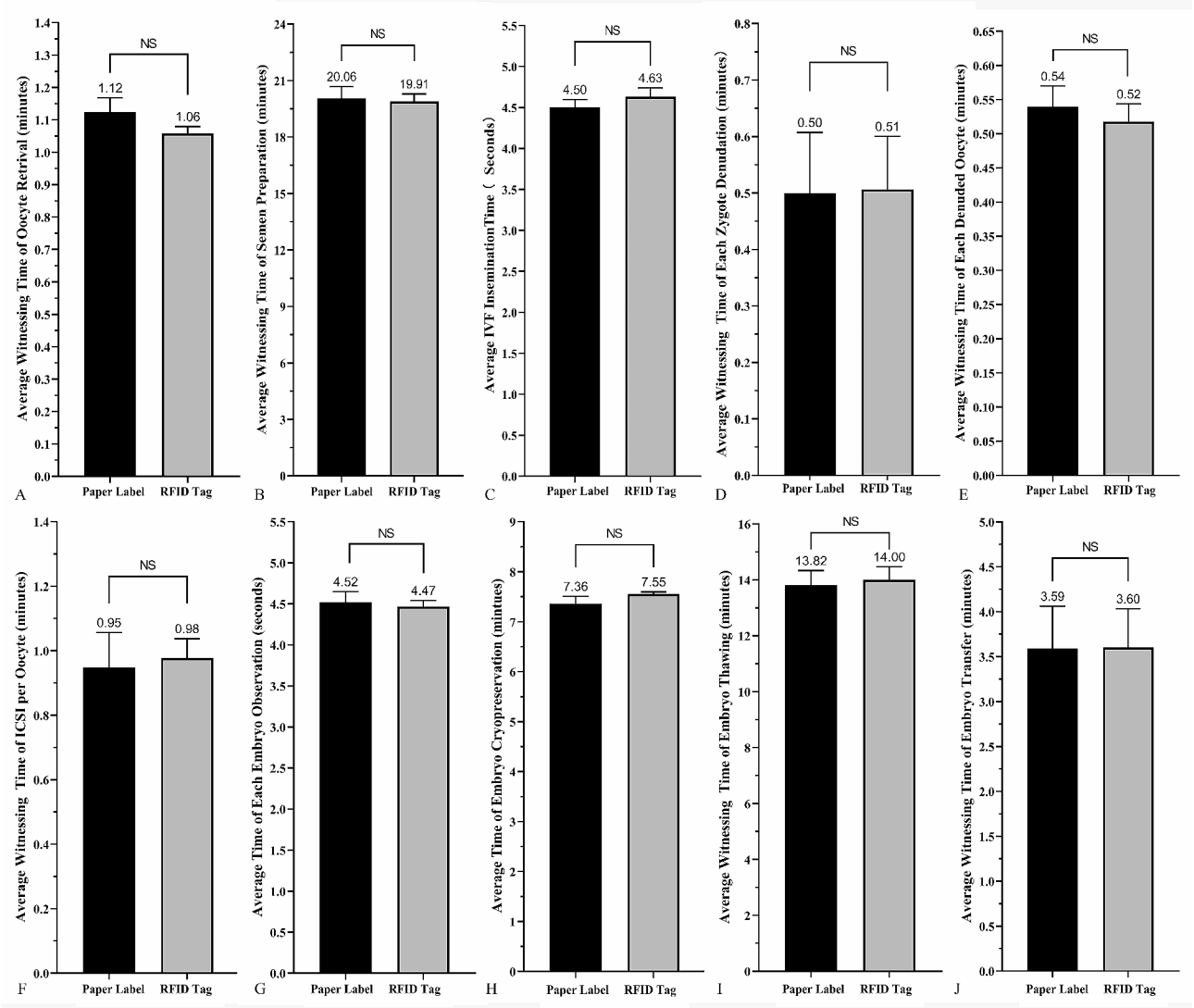

Fig. 4 Time Taken for Different Operations during Paper Label and RFID Tag Witnessing. During the operational process, the RFID tag witnessing system automatically records the time required for various procedures, such as oocyte retrieval (**A**), semen preparation (**B**), IVF (**C**), zygote denudation (**D**), oocyte denudation (**E**) and ICSI (**F**), embryo observation (**G**), embryo cryopreservation (**H**), embryo thawing (**I**), and embryo transfer (**J**). The embryologists manually record the time for each operation during paper label witnessing. All time values were recorded in minutes or seconds, and expressed as the mean ± standard deviation (SD). The unpaired t test was used to compare the time taken for each operation between the paper label and RFID tag groups. The unpaired t test was used to compare the time values between the paper label and RFID tag groups. Statistical significance was determined by p-values of less than 0.05. In cases where there was no significant difference, it was denoted by "NS" (no significant difference)

27.25±5.44 s ($P<0.0001$), 54.25±2.87 vs. 4.25±0.96 s ($P<0.0001$), 103.50±4.04 vs. 16.50±1.29 s ($P<0.0001$), and 66.75±6.50 vs. 8.75±0.96 s ($P<0.0001$), respectively. These findings suggest that the utilization of RFID tags provides a notable reduction in the time needed for data entry at each operational point, compared to traditional paper labels.

Average number and cost of paper labels and RFID tags for each cycle

The average number of RFID tags and paper labels used for each cycle is almost identical, with values of 10.22±1.44 and 10.33±1.20 ($P>0.05$), respectively (Table 1; Fig. 6; Supplementary Table 4). However, the cost per unit of RFID tags is significantly higher than that of paper labels, with prices of 140.35 and 0.057 US cents per piece, respectively. As a result, the total cost of RFID tags per cycle is approximately 14.35±2.02 US dollars, while the cost of paper labels per cycle is only 0.72±0.08 US dollars ($P<0.001$; Table 1; Fig. 6; Supplementary Table 4).

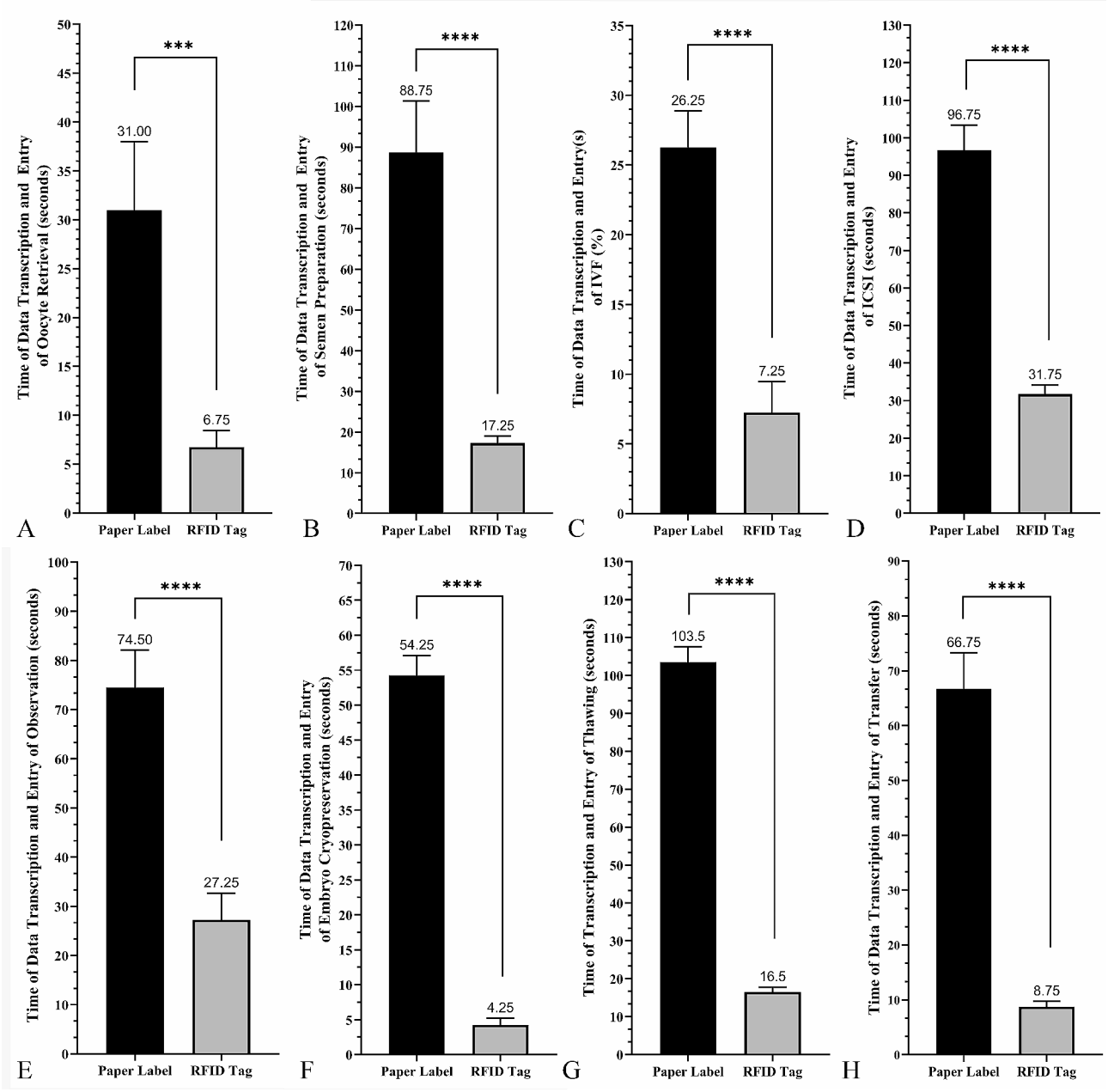

Fig. 5 Difference on the Time of Data Transcription and Entry through Paper Label and RFID Tag Witnessing. The time required for data transcription and entry of various procedures, such as oocyte retrieval (**A**), semen preparation (**B**), IVF (**C**) or ICSI (**D**), embryo observation (**E**), embryo cryopreservation (**F**), embryo thawing (**G**), and embryo transfer (**H**), was calculated during both paper label and RFID tag witnessing. All time values were recorded in seconds, and expressed as the mean ± standard deviation (SD). The unpaired t test was used to compare the time taken for each operation between the paper label and RFID tag groups. The unpaired t test was used to compare the time values between the paper label and RFID tag groups. Statistically significant differences were determined based on p-values of less than 0.001 and less than 0.0001, which were represented by the symbols "***" and "****" on the bars, respectively

Basic information of patients

The data presented in Table 2 shows that the average age of female patients in both the paper labels and RFID tag witnessing groups was similar, with values of 34.44±5.50 and 34.51±5.47 years, respectively. Furthermore, both groups displayed similar proportions of patients with female factor, male factor, and dual factors, except for idiopathic infertility, where a significant difference was observed (P=0.002).

Clinical results of in vitro fertilization and embryo transfer (IVF-ET)

The paper label and the RFID tag witnessing system groups consisted of 13,990 and 7,034 cycles, respectively

Table 1 Average number and cost between paper label and RIFD tag per cycle

	Average Number for Each Cycle	Unit Price (US Cents)	Cost (US Dollars)
RIFD Tags	10.22 ± 1.44^{a}	140.35	14.35 ± 2.02^{a}
Paper Labels	10.33 ± 1.20^{a}	0.057	0.72 ± 0.08^{b}

Values were expressed with mean ± standard deviation, and one-way ANOVA was used to analyze the number and cost of the RIFD tag/labels for each cycle. Statistical significance was indicated by p-values < 0.05. Different letters as superscripts indicate significant differences between two groups

Table 2 Demographic characteristics of patients included in this study

	Paper Labels	RIFD Tags	*P* Values
No. of Cycles(n)	13,390	7034	-
Average Age of Females (year)	34.44 ± 5.50	34.51 ± 5.47	= 0.378
Cause of Infertility	-	-	-
Female Factor (%)	7366(55.01)	3749(53.30)	= 0.154
Male Factor (%)	1614(12.05)	701(9.97)	= 0.274
Dual Factors (%)	1776(13.26)	830(11.80)	= 0.437
Idiopathic (%)	2634(19.67)	1754(24.94)	= 0.002

The $\chi 2$ test was utilized to analyze the percentages of infertility factors in patients and the unpaired two-tailed t test was employed to compare the average age of female patients. Statistical significance was indicated by p-values < 0.05

(Table 3). The data presented in Table 3 showed that the average number of oocytes per cycle was 8.87 ± 5.53 and 8.31 ± 6.00 in the paper label and RFID tag witnessing groups, respectively. There was a significant difference between the two groups ($P < 0.0001$). However, there were no significant differences in terms of normal fertilization rates (70.09% vs. 69.30%), usable embryos (81.99% vs. 81.81%), high-quality embryos (42.87% vs. 43.38%) on Day 3, and blastocyst formation (63.84% vs. 64.09%).

The embryo transfer procedure was conducted on either day 3 or day 5. Table 3 showed that the average age of female patients who received embryo transfer was 31.51 ± 5.58 and 32.37 ± 5.69 years in the paper label and RFID tag witnessing groups, respectively. There was a significant difference between the two groups ($P < 0.0001$). Additionally, the average number of transferred embryos was significantly different between the paper label and RFID tag witnessing groups (1.81 ± 0.45 vs. 1.41 ± 0.49; $P < 0.0001$). Although the number of transferred embryos decreased with increasing female age, no significant differences regarding implantation rate, clinical pregnancy

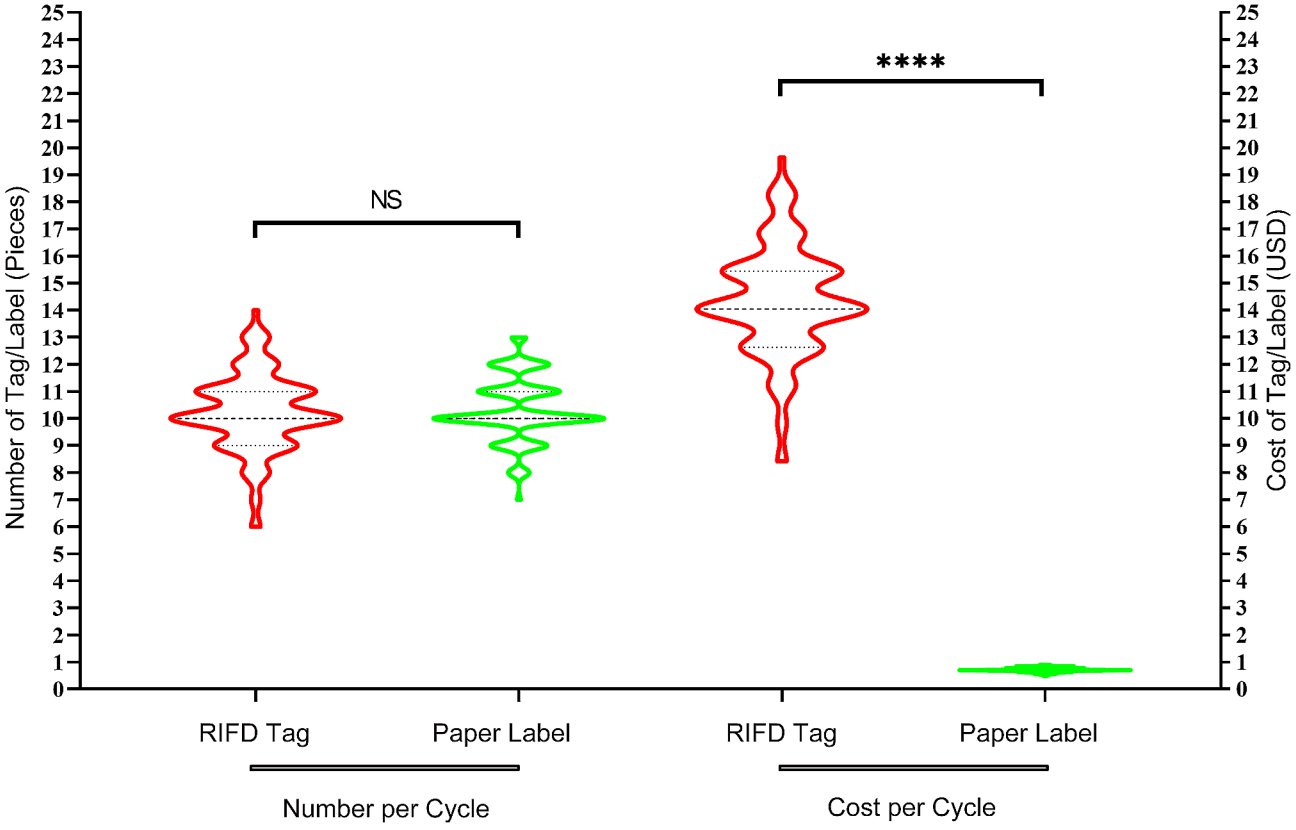

Fig. 6 Average Number and Cost of Paper Labels and RIFD Tags for Each Cycle. The average usage of paper labels and RFID tags per IVF cycle was 10.33 ± 1.20 and 10.22 ± 1.44, respectively. The cost per piece for RFID tags and paper labels was 140.35 US cents and 0.057 US cents, respectively. Consequently, the total costs associated with each cycle were 0.72 ± 0.08 for paper labels and 14.35 ± 2.02 for RFID tags, calculated in US dollars. The unpaired t test was used to compare the number and cost per cycle between the paper label and RFID tag groups. The symbol "***" on the bar represents a statistically significant difference, while "NS" indicates no significant difference

Table 3 Clinical results of in Vitro fertilization and embryo transfer

	Paper Label	RIFD Tag	*P* Values
Number of OPU Cycle(n)	13390	7034	-
Average Number of Retrieved Oocytes (n)	8.77 ± 5.53 (117376)	8.31 ± 6.00(58477)	< 0.0001
Normal Fertilization Rate (%)	82263(70.09%)	40524(69.30%)	= 0.154
Usable Embryo Rate on Day 3 (%)	67451(81.99%)	33151(81.81%)	= 0.419
High-quality Embryo Rate (%)	35263(42.87%)	17579(43.38%)	= 0.088
Blastocyst Rate (%)	43064(63.84%)	21245(64.09%)	= 0.229
Cycles of Fresh Embryo Transfer(n)	1388	1896	-
Average Age of Female (year)	31.51 ± 5.58	32.37 ± 5.69	< 0.0001
Average Number of ET Embryo (n)	1.81 ± 0.45(2508)	1.41 ± 0.49(2676)	< 0.0001
Implantation Rate (%)	1218 (48.56%)	1255 (46.90%)	= 0.230
Clinical Pregnancy Rate (%)	898 (64.70%)	1198 (63.19%)	= 0.373
Live Birth Rate (%)	744 (53.60%)	959 (50.58%)	= 0.087

The χ2 test was utilized to analyze the rates of fertilization, embryo development, clinical pregnancy and live birth and the unpaired two-tailed *t* test was employed to compare the number of oocyte or embryos, and the average age of patients. Statistical significance was indicated by p-values < 0.05

Table 4 Clinical results of frozen embryo transfer (FET)

	Paper Label	RIFD Tag	P Value
Average Age of Females (year)	33.89 ± 5.71	34.57 ± 5.52	< 0.0001
Total Number of FET Embryo(n)	16572	9778	
Number of FET Cycle(n)	9290	6495	
Average Number of Embryo (n)	1.78 ± 0.41	1.51 ± 0.50	< 0.0001
Implantation Rate (%)	7522(45.39%)	4526(46.29%)	= 0.158
Clinical Pregnancy Rate (%)	5591 (60.18%)	3957(60.92%)	= 0.349
Live Birth Rate (%)	4650 (50.05%)	3161(48.67%)	= 0.087

The χ2 test was utilized to analyze the rates of clinical pregnancy and live birth and the unpaired two-tailed *t* test was employed to compare the number of embryos and the average age of patients. Statistical significance was indicated by p-values < 0.05

rate, and live birth rate were found between two groups (Table 3).

Table 4 provides information on the 9,290 and 6,495 frozen embryo transfer (FET) cycles in the paper label and RFID tag witnessing groups, respectively. The average age of female recipients was 33.89 ± 5.71 years in the paper label group and 34.57 ± 5.52 years in the RFID tag witnessing group ($P < 0.0001$). Furthermore, the average number of embryos transferred per FET cycle was 1.78 ± 0.41 in the paper label group and 1.51 ± 0.50 in the RFID tag witnessing group ($P < 0.0001$). Similarly, although the number of transferred embryos decreased with increasing female age, there were no significant differences between the two groups in terms of implantation rate, clinical pregnancy rate, and live birth rate (Table 4).

Discussion

The procedures within the IVF laboratory are complex and multifaceted, necessitating the rigorous verification of the patient's identity at every stage. Even more serious is the fact that if any error in identity witnessing occurs during the operation process, it will inevitably lead to the mix-ups of gametes and the production of incorrect embryos. Moreover, mistakes that occur during the freezing, thawing, or transfer of embryos can have catastrophic repercussions for both patients and their families. To prevent errors in gamete and embryo matching, it is crucial to establish a dependable witnessing system. This system should be implemented at every stage of the ART treatment to ensure the safety of the procedure. Furthermore, it is imperative to have a minimum of two individuals present in the IVF laboratory at all times, especially during critical operations [13, 14]. A witness for IVF procedures can be anyone who has received the necessary training, although it is often another embryologist. Some centers have introduced trained laboratory assistants or dedicated personnel specifically hired for the purpose of witnessing during weekends to minimize the burden on the embryology staff [15]. Some IVF laboratories still rely on the practice of manually writing patient identification on test tubes, culture dishes, and stickers. However, this can pose a challenge for embryologists as handwriting can vary significantly between individuals, leading to errors in patient identification and causing visual confusion. This issue becomes particularly concerning when patients have similar names, making it difficult to accurately verify patient identity and their samples. To address this concern, many IVF laboratories are now shifting towards using printed labels or electronic tags for patient identification. This shift aims to improve accuracy and eliminate errors associated with handwriting variations. By labeling all tubes and dishes containing gametes and embryos and implementing manual double witnessing or electronic witnessing protocols, the risk of sample mismatching due to human error is significantly reduced [14]. However, in the process of implementing the double-checking only by eye-witness, errors from human factors are still inevitable. When faced with unfavorable conditions such as high workload, strict time limits, and high pressure, the eye-witness process of critical steps may only be a formality and cannot be strictly enforced [16].

It is important to emphasize that transitioning the traditional witnessing to electronic witnessing (verification)

system can greatly reduce the risk of adverse events [17, 18]. Furthermore, electronic witnessing systems are crucial in establishing a sample traceability system in IVF laboratory, and is able to ensure that the serious risks such as mix-up of sperm and oocytes or error in embryo transfer are minimized.

It should be highlighted here that our electronic witnessing and management systems have the capability to monitor the entire operating process to ensure strict adherence to SOP regulations. Compared to pure visual inspection, the RFID tag witnessing provides several advantages. Firstly, the printed RFID tags have clear and identifiable printed script, minimizing confusion of pure visual inspection. Secondly, RFID tags come with an error correction function that triggers an alarm in the event of a mismatch between two samples, effectively preventing potential errors in subsequent processes. The next, the electronic witnessing system automatically broadcasts accurate patient identity information, adding multiple layers of safeguards for laboratory safety. Additionally, the electronic witnessing system will not automatically push information to the next operation module if the previous process has not been completed. Hence, the workflow-based working mode facilitated by RFID tag witnessing plays a crucial role in preventing premature initiation of the next operation by embryologists. This workflow-based approach facilitated by RFID tag witnessing is essential in reducing the occurrence of risks associated with embryologist behavior.

In general, during the IVF process, it is crucial to verify the identification of each patient by cross-checking with labels. Therefore, multiple labels need to be printed in advance and affixed to various laboratory consumables such as semen collection containers, test tubes, and culture dishes prior to the operation. Before implementing RFID tags, our laboratory usually prints more than 10 adhesive paper labels and sticks in advance them onto each consumable, e.g. one for semen collection container, three for semen preparation test tubes, at least one for IVF dish, at least one for ICSI manipulation dish, at least one for culture dish for day 1–3 embryos, at least one for culture dish for day 5–6 embryos, two for embryo cryopreservation, two for embryo thawing, and one for embryo transfer according to the surgical schedule. However, if an error occurs during the labeling process, it is possible to mix up paper labels among different patients, thereby increase the risk of errors in subsequent laboratory operations. Consequently, once the double-inspection by eye is occasionally overlooked, it becomes easy to confuse the identities of different couples and result in serious errors. In particular, when dealing with patients who have similar or identical names, errors in the distribution of paper labels can lead to the inclusion of incorrect labels with similar names. This can cause considerable inconvenience during subsequent identification witnessing. Furthermore, if the embryologist is negligent once again, it could result in additional identification mismatches and heighten the risk of potential gamete mix-ups. To provide evidence of the effectiveness of RFID tag witnessing, our study simulated a scenario where patients with similar names had mixed labels or RFID tags. We found that visual inspection of multiple paper labels had a significantly high rate of missed detections, with an error correction rate of only 88.67%. However, the use of RFID tags for patient identification not only ensures rapid verification but also boasts a 100% error correction rate (as shown in Fig. 3). Thus, RFID tag witnessing could completely eliminate the risk of mismatches due to human negligence in the witnessing process.

Another objective of implementing the RFID tag witnessing system was to optimize the operational process and improve the efficiency of IVF lab. Our study findings (as shown in Fig. 6) demonstrate that the RFID tag witnessing system did not affect the duration of various operations. However, in comparison to the paper label witnessing (as shown in Fig. 5), we found that the application of RFID tags can significantly reduce the time required for paper medical record transcription and EMR data entry. It not only facilitated the verification of patient identification, but also allowed for automatically documenting the operational time and medical information. This eliminated the need for time-consuming handwritten medical records, resulting in more accurate and dependable operational information. By automatically recording and pushing data, the system reduced the chances of human errors associated with visual inspections and manual recording. Ultimately, the RFID tag witnessing system offered a more efficient and reliable approach to documentation and data management, surpassing the limitations of the traditional paper label system and paper medical records.

In addition, the efficiency is closely associated with the control of human error. The key advantages of utilizing an RFID tag system at IVF centers are to improve work efficiency and reduce the risk of human error [14, 19]. After RFID tags are integrated into electric medical record management system, the double witnessing by RFID tags is able to automatically broadcast the names of the couple, not only achieving fast cross-checking but also boasting a 100% error correction rate, which completely avoids the risk of errors due to simple human factors and ensures the safety and reliability during laboratory operation.

However, it is worth noting that the cost of using RFID tags is relatively higher compared to paper labels, resulting in an increase in consumable costs of approximately 14.35 US dollars per cycle (as indicated in Table 1).

Despite this cost difference, we highly recommend the adoption of electronic tags due to the paramount importance of safety and the protection of patient interests.

In addition to prioritizing safety and work efficiency, we have conducted an evaluation to determine whether the implementation of the RFID tag witnessing system has any impact on clinical outcomes. To this end, we conducted a retrospective comparative analysis to assess the influence of the RFID tag witnessing system on clinical treatment outcomes since October 2019. The clinical results indicate that the use of the RFID tag witnessing system does not have any noticeable effect on normal fertilization rates, usable embryo rates, high-quality embryo rates on Day 3 (%), and blastocyst rates when compared to the conventional paper label verification method (as shown in Tables 1 and 3). Furthermore, after the embryo transfer process, whether utilizing fresh or frozen-thawed embryos, and regardless of an increase in average maternal age and a decrease in the average number of transferred embryos, the implementation of the RFID tag witness system does not significantly impact embryo implantation rates, clinical pregnancy rates, and live birth rates (as presented in Tables 3 and 4).

In general, the integrated intelligent management of IVF laboratory involved a multiple of operations including oocyte retrieval, semen preparation, insemination, embryo culture, embryo observation, embryo cryopreservation. embryo thawing and embryo transfer. Firstly, after necessary internal training, a consensus must be reached as to the responsibilities of each embryologist (or technical personnel) in IVF laboratory, and each of them must strictly follow the same standard operating procedure (SOP). Secondly, while ensuring that double electronic witnessing is accurate and does not affect laboratory operations, technician should input all the data through every operation module in a real-time manner, and then promptly push them to the electronic medical record management system. This integrated management of IVF laboratory contributes to the communication between clinical and IVF laboratory by calling up the gamete and embryo information which is stored in the medical record management system.

In addition, as the team members, the embryologists provide a routine clinical laboratory service, involving culture and storage of embryos and also need to take part in a series of management and statutory data administration and communication tasks. It generally takes many days to complete the whole clinical task, sometimes resulting in delays sending patient correspondence and unavailability of clinical notes for multidisciplinary team (MDT) cycle-review meetings. Thus, the embryologists occasionally complained that transcribing data into paper medical records were time-consuming [12]. However, the real-time input of data can avoid the traditional recording method of paper medical records, saving time for technical staff, doctors, and nurses, and improving working efficiency. It can also prevent data loss, damage, tampering, and other issues that may occur in traditional recording methods, ensuring the security of medical record data. Moreover, real-time data entry is aimed at securely storing all medical information in the EMR management system and promptly reporting it to the government-managed database. This facilitates the timely analysis of various key performance indicators (KPIs) for quality control purposes. Additionally, it can accumulate more complete and accurate data, which is beneficial for conducting clinical research and scientific research in the field of assisted reproduction.

However, the present real-time input method in our system mainly relies on touch screen input, which may increase the risk of contamination for embryo culture. In the near future, we hope to introduce voice artificial intelligence to reduce this risk, making the system more intelligent, efficient and practical in clinical application [20]. Additionally, the limited reading range of low-frequency RFID tags poses a significant constraint, and their vulnerability to physical damage, such as from overbending or exposure to ultra-low temperatures, may occasionally lead to very few tags unreadability. Moreover, the system for RFID tag witnessing and real-time data entry requires a reliable network connection; any network interruption could potentially halt the operations of the entire IVF laboratory. Lastly, the intolerability of RFID tags with ultra-low temperatures reaching −196 ℃ rules out their application in embryos or gametes cryopreservation as the identifiers.

Conclusion

In summary, the implementation of this workflow-based real-time witnessing and management system creates a secure environment for IVF laboratory operations and reduces potential risks for infertility patients during clinical treatment. It effectively prevents errors and omissions of operation, while also facilitating rapid real-time data recording for the electronic medical record management system. This real-time information entry also ensures the accuracy and reliability of the medical data, ultimately enhancing work efficiency. Therefore, this workflow-based electronic witness and management system holds significant practical value and is worth of being strongly recommended for wider adoption and implementation during clinical treatment process.

Abbreviations

ART	Assisted Reproductive Technology
IVF	In Vitro Fertilization
ESHRE	The European Society for Human Reproduction and Embryology
FLASEF	The Federacion Latinoamericana de Sociedades de Esterilidady Fertilidad of Europe and South America

HFEA	The Human Fertilisation and Embryology Authority of the Unites Kingdom
CSRM	China Society of Reproductive Medicine
EWS	Electronic Witnessing System
RFID	Radio Frequency Identification
ICSI	Intracytoplasmic Sperm Injection
MRN	Medical Record Number
ID	Identification
EMR	Electronic Medical Record
SD	Standard Deviations
COC	Cumulus Oocyte Complex
MII	Metaphase II
FET	Frozen Embryo Transfer
MDT	Multidisciplinary Team
KPI	Key Performance Indicator

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Supplementary Material 6

Supplementary Material 7

Supplementary Material 8

Supplementary Material 9

Supplementary Material 10

Supplementary Material 11

Supplementary Material 12

Supplementary Material 13

Supplementary Material 14

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Author contributions
MXJ, LG, SL, XFX and WC participated in the design of the IVF laboratory management system. MXJ, LG, SL, GLZ, YMX, XHZ and YYS participated in the implementation of this management system. MXJ, NQC, SQC, GLZ, XHZ, YMX and LHF collected and analyzed the patient data. MXJ was a major contributor in writing the manuscript and drew all the figures. All authors provided substantial suggestions and edits for the writing of the paper. All authors approved the submission of this paper.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Data analysis of patient medical records in this retrospective study was performed in accordance with the Declaration of Helsinki and was approved by the ethics committee of Guangdong Second Provincial General Hospital (No. 2023-KY-KZ-179). The need for written informed consent to participate was waived by the ethics committee Guangdong Second Provincial General Hospital due to retrospective nature of the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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References

1. Bender L. To err is human: ART mix-ups - a labor-based, relational proposal. J Gend Race Justice. 2006;9(3:):443–508.
2. Sakkas D, Barrett CB, Alper M. O-068 to err is human, even in IVF: a review of non-conformances/errors in 31,715 in vitro fertilization (IVF) treatment cycles. Hum Reprod. 2014;29(Suppl 1):P29.
3. Ding CH, Xu YW. Prevention of adverse accidents in vitro fertilization laboratory. Chin J Practical Gynecol Obstet. 2018;34(6):586–91. (in Chinese).
4. Adams DS, Carthey DJ. IVF witnessing and electronic systems final report. In. Edited by HFEA. https://www.hfea.gov.uk/docs/Witnessing_samples_id_report.pdf; 2006.
5. Magli MC, Abbeel EVD, Lundin K, Royere D, Elst JVD, Gianaroli L. Embryology fCotSIGo: revised guidelines for good practice in IVF laboratories. Hum Reprod. 2008;15(10):2241–6.
6. Nyboe Andersen A, Goossens V, Bhattacharya S, Ferraretti AP, Kupka MS, de Mouzon J, Nygren KG. Assisted reproductive technology and intrauterine inseminations in Europe, 2005: results generated from European registers by ESHRE: ESHRE. The European IVF Monitoring Programme (EIM), for the European Society of Human Reproduction and Embryology (ESHRE). Hum Reprod (Oxford England). 2009;24(6):1267–87.
7. Embryologist Group CSoRMCMA. Consensus on human IVF-ET laboratory manipulations (2016). J Reprod Med. 2017;26(1):1–8.
8. Brison DR, Hooper M, Critchlow JD, Hunter HR, Arnesen R, Lloyd A, Horne G. Reducing risk in the IVF laboratory: implementation of a double witnessing system. Clin Risk. 2004;10(5):176–80.
9. Hur YS, Ryu EK, Park SJ, Yoon J, Yoon SH, Yang GD, Hur CY, Lee WD, Lim JH. Development of a security system for assisted reproductive technology (ART). J Assist Reprod Genet. 2015;32(1):155–68.
10. Perrin RA, Simpson N. RFID and bar codes–critical importance in enhancing safe patient care. J Healthc Inf Manag. 2004;18(4):33–9.
11. Sterckx J, Wouters K, Mateizel I, Janssens R, Tournaye H, Verheyen G, De Munck N. P-780 ten years electronic witnessing in the IVF laboratory. Hum Reprod 2022, 37(Suppl. 1).
12. Wood L, Proudlove N. Doing today's work today: real-time data recording and rolling audit in an IVF clinic. BMJ open Qual 2022, 11(3).
13. Dyer C. Human error and systems failure caused IVF mix up. BMJ (Clinical Res ed). 2004;328(7455):1518.
14. Forte M, Faustini F, Maggiulli R, Scarica C, Romano S, Ottolini C, Farcomeni A, Palagiano A, Capalbo A, Ubaldi FM, et al. Electronic witness system in IVF-patients perspective. J Assist Reprod Genet. 2016;33(9):1215–22.
15. Sergi N, Carme N, Oriol P, Leonardo B, Josep S, Rodrigo G-M, Jaume E, Abdelhamid E, Antonio PJ. Lluïsa P-G: Barcode tagging of human oocytes and embryos to prevent mix-ups in assisted reproduction technologies. Hum Reprod. 2014;29(1):18–28.
16. Toft B, Gooderham P. Involuntary automaticity: a potential legal defence against an allegation of clinical negligence? Qual Saf Health Care. 2009;18(1):69–73.
17. Rienzi L, Bariani F, Dalla Zorza M, Romano S, Scarica C, Maggiulli R, Nanni Costa A, Ubaldi FM. Failure mode and effects analysis of witnessing protocols for ensuring traceability during IVF. Reprod Biomed Online. 2015;31(4):516–22.
18. Holmes R, Wirka KA, Catherino AB, Hayward B, Swain JE. Comparison of electronic versus manual witnessing of procedures within the in vitro fertilization laboratory: impact on timing and efficiency. Fertility Steril Rep. 2021;2(2):181–8.
19. Thornhill AR, Brunetti XO, Bird S, Bennett K, Rios LM, Taylor J. Reducing human error in IVF with electronic witnessing. Fertil Steril. 2011;96(3–supp–S):S179–179.

20. Cho A, Min IK, Hong S, Chung HS, Lee HS, Kim JH. Effect of applying a real-time medical record onput assistance system with voice artificial intelligence on triage task performance in the emergency department: prospective interventional study. JMIR Med Inf. 2022;10(8):e39892.

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