Short Communication

Outpatient Follicle Monitoring: A Plea for Standardization in Ultrasound Based Follicle Monitoring and Data Transfer

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Abstract

Background: The complexity of assisted reproductive technology (ART) increased during the last decades. New scientific and medical findings as well as the statutory requirements for improving the safety and the outcome of ART were the main impetus for its development. While therapy planning is done and ART is used by the IVF centers, the medical support and monitoring of patients is conducted by referring gynecologists. Reported follicle measurements by the gynecologist allow the adoption of the therapy plan. Most notably, the crucial aspect is processing and interpretation of ultrasound scan (US). The results of the received US, the transfer of data between IVF center(s) and referred physician(s) as well as the subjective interpretation often culminate in interpretation and logistical problems. This might increase the error probability with considerable detriments for the patients and ART outcome.

Methods: The follicle monitoring was performed using Voluson I ultrasound system combined with SonoAVC® software. Results were communicated via DICOM language to DynaMed® software, a medical program for managing an IVF center with seamless integration of all processes needed for an accurate and precise workflow.

Results: In this study, no loss of data was detected. All data were integrated by DynaMed® software and were recallable in a fast and easy manner.

Conclusion: The broad usage of Voluson I ultrasound SonoAVC® software and communication of the results via Picture Archiving and Communication System (PACS) server between the IVF center and local gynecologist would provide more assistance for the patients and consequently the ART outcomes can be improved.

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Introduction

The demands for assisted reproductive technologies (ART) have increased markedly during recent years. New scientific and medical findings as well as the statutory requirements for improving the safety and the outcome of ART therapy were the main impetus for its development. Therefore, it is essential that therapy planning and ART be conducted at highly specialized IVF units. However, during an IVF therapy, decentral gynecologists are often involved in follicle growth monitoring. In this way, on the one hand, the IVF centers can be assured about the results. Results are communicated to the IVF clinics in order to receive instructions on how to proceed with the therapy plan in terms of further dosing of follicle stimulating hormone, stimulation period and the time-point of initiating final oocyte maturation. On the other hand, this practice might also increase the inter-observer error rate. It is widely accepted that follicular assessment is a rather dif-

ficult and inaccurate task (1, 2). Different institutions might use different US techniques and additionally there are various ways of interpretation of ultrasound scans. However, such an inter-observer variability of ultrasound scans can be eliminated by standardized procedures and electronic communication of reported data. Previously, we demonstrated the benefit of Voluson I ultrasound system plus SONOAVC® in regard to the fertilization rate of retrieved oocytes (3).

In this study, we reported the impact of standardized procedure by using 3D-ultrasound for real-time volumetric images. The subsequent transmission of these data was done through DICOM language and a secured connection (Virtual Private Network (VPN) tunneling).

Methods

The platform of our clinic encompasses 6 IVF centers in 5 European countries. Follicle monitoring was performed using Voluson I ultrasound system (GE Medical Systems, Kretztechnik, Zipf, Austria) as previously published (1) combined with SonoAVC® software (General Electric Company, New York, USA). The results were communicated via DICOM language to DynaMed® software (IMA-Systems Information-Technology GmbH, Bregenz, Austria) for managing an IVF center with seamless integration of all processes needed for an accurate and precise workflow.

Results

Overall, 124 follicle scans were performed in one of our IVF centers in a standardized and objective way using sonography-based automated volume count. The simple, fast and accurate transmission of data of follicle volumes between our centers or between local gynecologist and our IVF centers is demonstrated in this article (Figure 1). No loss of data was detected. All data were integrated by the in-house software and were recallable in a fast and easy manner. When US scans were performed with sonography-based automated volume count by our satellite centers or local gynecologists, they were transmitted to our center in Bregenz/Austria via DICOM. We observed no severe discrepancies in follicle number and size in our measurements. Moreover, we mostly observed cases with maximal deviation as is demonstrated in our paper (Figure 2). A 37- year- old woman was stimulated on October 2012 using a standard long protocol. First, two US scans were performed by an external fertility center (10/10/2012 and 10/12/2012, respectively). Only 5 follicles were visible, but 3 of those obviously reached critical diameters of 16-20 *mm* (2), while the other two had diameters of 10 and 11 *mm* respectively. Thickness of patient's endometrium was calculated and it was 11 *mm*. Data were communicated to our IVF clinic via telephone. Based on these results, final oocyte maturation and the induction of ovulation were performed with 2x 5,000 *IU* hCG (Choriomon®, IBSA/Switzerland). On the day of oocyte pick-up (10/16/2012), when we performed an US scan, the situation completely differed from our expectations. The thickness of the endometrium was 18.2 *mm*. We found only one follicle with a diameter of 16 *mm*, but a large cohort of 12 small follicles had diameters between 6-15 *mm*. The outcome was poor as expected. Only 3 oo-

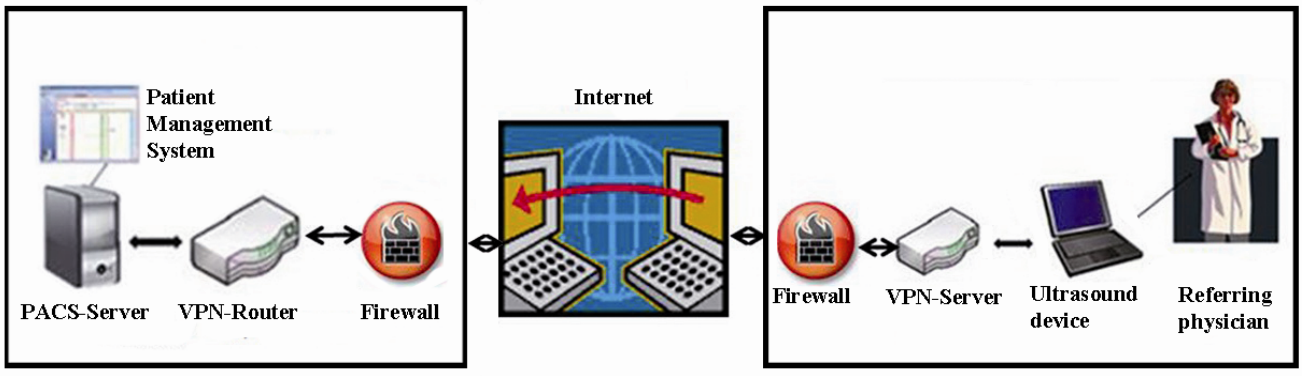

Figure 1. Scheme of patient data transmission between local gynecologist and IVF center. The Ultrasound device (USD) submits the results of the medical examination (follicle volumes and endometrium measurements) to PACS server. The USD queries work lists and patient's data from the PACS server. All data transmission between USD of the referring physician and PACS server in the clinic is done by VPN tunneling. All data is encrypted and safe from unauthorized access. IPsec (Internet Protocol Security) with encryption key length of approximately 2048 bits allows the secure Internet protocol by communication by authentication, integrity and encrypting the data during the communication. The encryption key alters every second

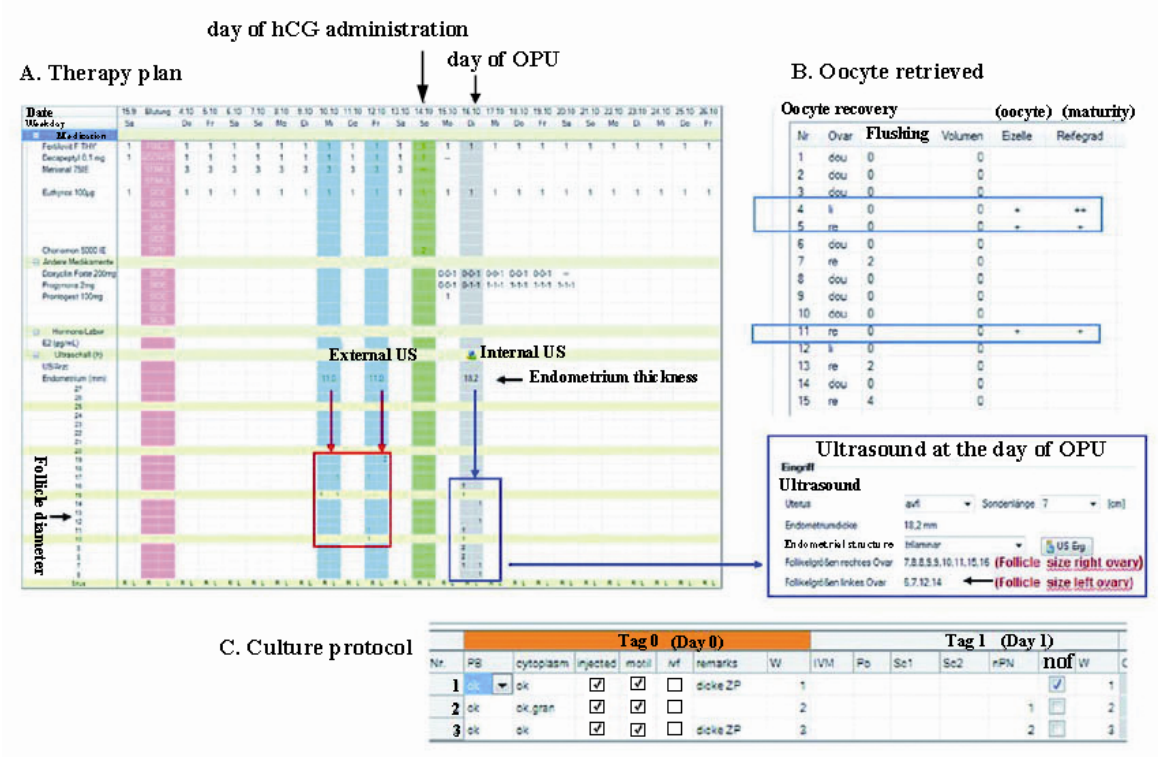

Figure 2. Stimulation, US, oocyte pick-up (OPU) and culture protocol of the patient. The external US measurements are boxed in red, internal US performed with Voluson I ultrasound system plus SONOAVC® is boxed in blue.
+/++ represents the grade of oocyte maturity

cytes were retrieved and only one of those was mature (metaphase II). Two oocytes were fertilized on day 1 after Intracytoplasmic Morphologically Selected Sperm Injection (IMSI). This case clearly demonstrates that fertility treatment requires mutual interaction between all involved physicians who might be separate from each other by hundreds of kilometers. Subjective interpretation of endometrium and follicle scans and transmission of data to the IVF centers might influence the ART outcome in a negative manner as we demonstrated here.

Discussion

According to estimates of the World Health Organization, 2-10% of couples worldwide are unable to conceive a child and a further of 10-25% suffer from secondary Infertility. Since the 1978 breakthrough in the field of reproductive medicine, when the first *in vitro* baby was born (5), ART has become the routine procedure however, the practice in the field of reproductive medicine is definitely not a simple one. Sophisticated techniques such as improved follicle monitoring by 3D Ultrasound, PGD, gamete and embryo cryopreservation using vitrification have provided new options for physicians and biologists and new hope for infertile couples. Facing the high cost of an IVF therapy and the potential health risks for patients and offspring, several countries have introduced some requirements for treatment and outcome monitoring for IVF clinics within the last few years (6, 7). Therefore, quality and quality control play more important roles in assisted reproduction. A crucial aspect in improving quality is standardization -a consist process with little variation as possible. Second, processes should be always optimized and error rates should be minimized. Regarding our experience with external US follicle scans and telephone consultation for communication of US data, there are still several weak points in the application of ART.

Three dimensional (3D) Ultrasound was found to be superior to 2D US in reproductive medicine. Moreover, several publications demonstrated the high accuracy of the sonography-based automated volume count (8-10). The simplification of follicle scan through reporting objective and standardized information to the software designed to integrate all processes in an ART cycle saves time, increas-

es accuracy and minimizes inter-observer error rates. The difference in operative experience besides different ways of interpretations of ultrasound scans, and the inter-observer variability can lead to too early or too late hCG administration. Furthermore, other factors are involved in this procedure.

Conclusion

As the overall success rates of ART are still unsatisfactorily low, possible weak points in the IVF process should be eliminated. The advantage of PACS is the fast data transfer, the fast and secure data storage and the easy access. Thus the need to manually file or retrieve is eliminated. Digital Imaging and Communications in Medicine (DICOM) has emerged to increase the efficiency of the distribution of information (11). The pivotal question is whether we can use this technique for ultrasound based follicle monitoring or not. A consequent document control is a crucial part of a good quality management system (12). With the demonstrated system, all data can be easily transmitted and stored and are easily recallable. The objective and standardized information exchanges and documentation would not only elevate the success rate of an ART therapy but would lead to more legal certainty in case of putative legal dispute(s).

Conflict of Interest

The authors declare no conflict of interest.

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