Original Article

Improving Fertility Treatment Documentation – A Survey

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Abstract

Background: Many couples do not have adequate documentation following fertility treatments. **Aims:** To conduct a survey to understand the information needs of assisted reproductive technology physicians when assessing the reasons affecting treatment outcomes after intrauterine insemination (IUI) and *in vitro* fertilisation (IVF). **Settings and Design:** Online survey. **Materials and Methods:** Anonymous online survey of 14 parameters related to IUI treatment and 21 parameters related to IVF treatment, followed by recommendation of selected parameters for routine documentation. **Statistical Analysis Used:** Frequency distribution calculation of responses. **Results:** For IUI, total motile sperm count and post-wash sperm count and motility and for IVF, the quality and number of gametes, embryo number and morphology were the most important parameters. **Conclusion:** The study creates recommendations for the minimum information desirable in the fertility treatment documentation given to the couple undergoing treatment.

Keywords: *Documentation, in vitro fertilisation, intrauterine insemination*

Introduction

Fertility treatments are increasingly becoming common as a result of easier availability, affordability and patient awareness. In India, the infertile couple has the freedom to choose the treatment centre and it is not infrequent to see couples moving from one clinic to another, if the initial treatment is unsuccessful.

It is usual for the treating clinician to encounter patients with no documentation of their previous fertility treatments. It is also common to see patients who do have a treatment record, but more often than not, the details are inadequate to judge the reason for the failure of previous treatments. This is especially important as the odds of a patient not conceiving are always higher than her chances of getting pregnant in an intrauterine insemination (IUI) or in an *in vitro* fertilisation (IVF) cycle.[1,2]

The Indian Society of Assisted Reproduction came out with the Consensus Guidelines on Safety and Ethical Practices in IVF Clinics in 2021.[3] The Government of India issued the Assisted Reproductive Technology (Regulation) Act, 2021, and the Surrogacy (Regulation) Act, 2021 to regulate the practice of fertility treatments in the country.[4,5] Although this guideline and these laws have come out comprehensively on many areas of fertility treatment, there has been little said about empowering the infertile couple by giving them access to proper documentation about their treatment.

Although some centres do give a detailed treatment summary, many do not. This could be because of a lack of legal compulsion, poor patient awareness, fear of litigation or simply indolence on part of the treating clinical team. The lack of a standardised format for treatment reporting and the absence of uniformity in nomenclature compound the problem. It is paramount that the report should be brief, easy to prepare and encompasses all important facts related to the treatment.

A survey was therefore conducted by sending a questionnaire to clinicians performing assisted reproduction techniques. The aim of the study was to find those factors which clinicians considered as

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important determinants affecting the success of two common fertility treatments – IUI and IVF.

Materials and Methods

An anonymous online survey was created using the QuestionPro survey web application (QuestionPro, Level 4, 114 William Street, Melbourne, Victoria 3000, Australia) and sent directly to 90 clinicians in India and the United Kingdom through an instant messaging application. The clinicians approached for the survey were into a regular practice of assisted reproduction techniques for more than 5-year duration. The questionnaire consisted of 14 parameters related to IUI treatment and 21 parameters related to IVF treatment. The clinician responding to the survey was asked to mark by selecting one of the three variables – quite important, somewhat important and not important against each of these data variables. The aim was to identify the importance of each of these parameters as a reason for treatment failure or success. Survey participation was entirely voluntary. This data was coded, tabulated and categorised. The frequency distribution calculation of responses based on the variables was performed using Microsoft Excel.

Based on the findings of the survey, five and ten most important parameters surveyed were incorporated to create a treatment summary for IUI and IVF, respectively. This would ensure that no important information was left out and that the time and effort taken to create a treatment summary were brief and reasonable.

Institutional review board approval was not sought, as the study did not involve the collection of patient data or participation.

Results

Fourty-seven out of 90 clinicians who were approached anonymously completed the survey (52.2%). With regard to IUI, the most vital data which were considered as an important determinant of treatment success were the total motile sperm count (TMSC) (91.3%) and post-wash sperm count and motility (89.4%). The other key factors were the number of follicles larger than 16 mm and the endometrial thickness at the time of IUI (both 78.7%) [Table 1].

When IVF treatment was considered, the quality (95.7%) and number (89.4%) of gametes collected along with embryo number and morphology at the time of transfer (95.7%) were assessed to be the most important parameters. The other significant data which were of interest included the nature of the ovulation trigger (84.4%), starting dose of gonadotropins and the ease of doing the embryo transfer (both 82.9%) [Table 2].

Discussion

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, give a brief guidance on maintaining patient records and a format of a medical record in 'Appendix 3' of the regulations.[6] The Charter of Patients' Rights by the National Human Rights Commission (India) emphasise the 'Right to records and reports' under the section on 'Rights of patients'.[7] These two documents offer only broad guidelines and we do not have a specific national guidance on treatment summaries for patients following Assisted Reproductive Technology (ART) treatments. Any such record should not only give a synopsis of the treatment cycle for the understanding of the infertile couple but also help a reviewing fertility specialist comprehend the intricacies of the treatment. This survey helps understand the nature of information needed by ART practitioners to help them assess two common fertility treatments and the possible reasons which might have contributed to their failure.

Regarding IUI, the TMSC and the post-wash sperm count with motility were the parameters considered most important. Both these have been considered important prognostic factors, with an emphasis on cut-offs to identify poor prognosis patients for IUI treatment.[8,9] The other important parameters were follicular number and endometrial thickness. Multi-follicular growth is associated with an increase in pregnancy rate, although with a higher risk of multiple pregnancies.[10] Endometrial thickness, however, has not been well correlated with pregnancy outcomes, though a thin endometrium needs further evaluation.[11] With IVF, the quality and quantity of gametes and embryos were considered the most important factors determining the success of treatment. This result was not unexpected, as most studies have considered these factors along with the woman's age as the most significant predictors of treatment success.[12,13]

As part of patient documentation, there are no restraints in including all 14 and 21 parameters related to IUI and IVF treatment, respectively. However, to keep the treatment summary concise as well as informative, it is suggested that at a minimum, five and ten most important data parameters, which are likely to be the most important should be included in IUI and IVF treatment summaries, respectively [Tables 3 and 4]. Additional or all data might be included at the clinician's discretion to enhance the amount and quality of information given to the patient.

It is important not only just to develop a practice of proper documentation but also to ensure that all patients are handed over documentation about their treatment, upon its completion. Unfortunately, the concept of

Table 1: Importance of selected parameters with respect to success of IUI treatment

Parameter	Response	Quite important	Somewhat important	Not important
Drugs used for stimulation	46	25	15	6
Endometrial thickness at the time of IUI	47	37	7	3
Number of follicles larger than 16 mm	47	37	10	0
Drug used for ovulation trigger	47	22	21	4
Time between trigger and IUI	47	26	18	3
Pre-wash sperm count and motility	46	31	15	0
Post-wash sperm count and motility	47	42	4	1
TMSC	46	42	4	0
Catheter used for IUI	46	8	24	14
Speculum used for IUI	47	5	15	27
Media used for IUI preparation	47	26	20	1
Technique used for IUI preparation	47	16	23	8
Ease of performing IUI	47	19	21	7
Nature of luteal support	47	22	22	3

IUI=Intrauterine insemination, TMSC=Total motile sperm count

Table 2: Importance of selected parameters with respect to success of IVF treatment

Parameter	Response	Quite important	Somewhat important	Not important
IVF protocol	47	37	10	0
Gonadotropins used	47	33	13	1
Starting dose of gonadotropins	47	39	8	0
Dosage of gonadotropins per day	47	35	11	1
Total dose of gonadotropins during treatment cycle	47	25	17	5
Drug used to trigger ovulation	45	38	7	0
Interval between ovulation trigger and oocyte retrieval	46	38	8	0
Endometrial thickness at the time of oocyte retrieval	47	21	12	14
Number of follicles at the time of oocyte retrieval	47	36	11	0
Number of oocytes retrieved	47	42	5	0
Type of needle used for oocyte retrieval	47	9	22	16
Quality of sperms and oocytes	47	45	2	0
Type of fertilisation – IVF or ICSI	47	34	11	2
Fertilisation rate (2PN)	46	41	4	1
Cleavage rate	46	40	5	1
Embryo number and morphological grade at the time of transfer	47	45	2	0
Culture media used for embryo culture	47	25	17	5
Catheter used during transfer	46	20	19	7
Ease of doing embryo transfer	47	39	8	0
Whether embryo transfer was done under ultrasound guidance	47	36	8	3
Luteal support	47	38	9	0

IUI=Intrauterine insemination, IVF=*In vitro* fertilisation, ICSI=Intracytoplasmic sperm injection, 2PN=Two pronuclei

self-regulation is wanting in our system and there might be a need to create a push to promote this practice. This could either be in the form of a government legislation to amend the Assisted Reproductive Technology (Regulation) Act, directives from the Ministry of Health, or guidelines from the ART bodies. This would make it obligatory for the health provider to ensure that patients are provided with their records in both letter and spirit. This is especially important in the context of ART, since many treatments are performed without a need for in-patient hospitalisation, thus a legal requirement for giving an in-patient summary is lacking. Education and awareness must be given to infertile patients to ensure that they collect and preserve their investigation reports and treatment records.

The strengths of the study included limiting the participants to ART clinicians and ensuring that they have been in the specific field for a long enough time to understand the nuances of treatment and the difficulties faced while seeing patients following treatment failures at other centres.

Table 3: Intrauterine insemination treatment summary

Name:	Wife	Husband
Age:	Wife	Husband
Hospital No:		
Date:		
No of follicles >16 mm:		
Endometrial thickness:		
Pre-wash sperm count and motility:		
Post-wash sperm count and motility:		
Total motile sperm count:		
Comments:		

Table 4: *In vitro* fertilisation/intracytoplasmic sperm injection treatment summary

Name:	Wife	Husband
Age:	Wife	Husband
Hospital No:		
Date:		
IVF protocol:		
Gonadotropin and starting dose:		
Ovulation trigger, date and time:		
Number of follicles:		
No of oocytes retrieved and quality:		
Sperm count and quality:		
Fertilisation and cleavage:		
Number of embryos transferred with grading:		
Ease of doing transfer:		
Luteal support:		
Comments:		

There have been differing perceptions about ideal survey response rates and a survey with close to half the numbers not responding might be considered a weakness of the study. Another significant concern has been a small sample size. As the study involved a limited number of ART clinicians who were invited by the author for the study, the possibility of both participation and selection bias exists. The information and recommendations from this study could be evaluated and improved on in a larger study.

Conclusions

This study creates recommendations for the minimum information desirable in treatment documentation for IUI and IVF, which is handed to the infertile couple undergoing treatment. Adoption of these suggestions will help to standardise treatment documentation and improve patient care.

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Conflicts of interest

There are no conflicts of interest.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article.

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