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Evaluation of ovulation by urinary LH surge kits versus transvaginal sonography

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ABSTRACT

Objectives: The study was conducted to evaluate the efficacy of urinary LH surge kits and transvaginal ultrasonography (TVS) to detect ovulation in induced cycles and to compare the ovulation rates by both methods.

Materials and Methods: Prospective observational cohort study on 144 women with anovulatory infertility aged 18-35 years, fulfilling the inclusion criteria were given letrozole for ovulation induction. All were randomly divided into two groups. Group 1 women were asked to check ovulation by urinary LH surge kits and group 2 women were called for follicle monitoring by TVS.

Results: Letrozole has no negative effect on the endometrium; the induced cycle has a larger diameter of follicle (median: 22 mm). In the induced cycle ovulation occurs later compared to normal cycle (D-16) and half of the women had a BMI more than the recommended WHO criteria (average was 25.28 kg/m2). Number of letrozole cycles (p=0.2642), dose requirement (p=0.0812) and pregnancy rates (10.26% versus 18.19%) were comparable in both groups.

Conclusions: TVS is objective, accurate, and thus a standard modality for ovulation detection. LH surge kit is subjective, having more chances of error but can be used as a good alternative in certain settings like women from the remote area, and women having fear of invasive modality.

1. Introduction

Infertility is described as, no pregnancy after 12 months of unprotected sex and influences about 12-15% of couples. Usually up to 90% of couples conceive in 12 months of marriage and rest of them within next 9 months. As of now the commonest causes of infertility are grouped in female factors (30-40%), male factors (30-40%), and rest is unexplained. In females the leading cause is ovulatory disorders. Assessment of infertility is done by knowing the above-mentioned factors. Ovulation detection, tubal patency tests and semen analysis are the most common investigations to know the aetiology of infertility. To know the ovulation, the most common method used is transvaginal sonography (TVS). Other modalities are urinary luteinizing hormone (urinary LH) detection, urinary follicular stimulating hormone (FSH) detection, serum progesterone levels, analysis of cervical mucus and salivary ferning. Ideal approach means, easy availability, non-invasiveness, devoid of cost, easy to use, timely detection and sensitive. Same is true for the methods to detect ovulation as well as there should be appropriate fertility window (begins 2-3 days earlier than rupture of follicle and continues 1-2 days after ovulation).[1] By TVS detailed follicular monitoring, preovulatory changes and ovulation can be detected very precisely. LH surge in urine may be very sensitive, convenient, non-invasive, and precise method for ovulation detection. From new menstrual cycle day 10 to day 11 (day 1 is described as the first day of menses) or four days earlier than the expected day of ovulation,

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ladies can measure their LH in urine a couple of times a day. Urine LH kits can detect LH levels as little as 22 mIU/mL, even as the normal levels of LH in urine varies from 20-100 mIU/mL. According to reports, there was a 20 ± 3 hour (95% CI 14-26) median time interval between the follicle formation for LH and the detection of a rupture. Additionally, a study on infertile women found that the urine LH test's sensitivity, specificity, and accuracy for ovulation detection were 1.00, 0.25, and 0.97.[2] Because a positive result indicates ovulation within 48 hours, the US National Academy of Clinical Biochemistry Laboratory Medicine's Practice Guidelines advise a urine LH test. Since the LH spike in urine is more reliable, less expensive, and less invasive than ultrasound, many studies have been done to use it to identify ovulation.[3–7]

It was observed that if single intercourse is made from 2 days prior and until the day of ovulation, clinical pregnancy rate is highest. This time can be best predicted by urinary LH surge kits.[8] Since urinary LH surge kits are superior to TVS in terms of accuracy, affordability, ease of use, and non-invasiveness, we intend to investigate their efficacy in ovulation detection.

2. Materials and Methods

A prospective observational cohort study was conducted from May 2019 to April 2021, in the department of Obstetrics and Gynecology, LLRM Medical College affiliated to SVBP Hospital in Meerut (UP). One hundred and forty-four women with anovulatory infertility, who met the inclusion criteria were enrolled. Before starting the study, institutional ethical committee clearance was obtained. Written and informed consent was taken from every woman before enrollment.

2.1. Inclusion criteria

Women between the ages of 18 and 35 who had anovulation and had bilateral tubal patency as well as no other gynecological, medical, or surgical conditions were included. Additionally, the husband's seminogram should fall within the usual limits. For ovulation induction, letrozole tablets (2.5–7.5 mg starting on day 2 or 3) were utilized in every instance. Using the chit method, they were divided into two groups at random. The individuals in Group 1 selected the LH surge kit chit. They were instructed to use urinary LH surge kits to monitor ovulation starting on day 12 and continuing until the test yielded a positive result at around midday. The test was terminated, and the cycle determined to be anovulatory if it was still negative by day 25.

Group 2 consisted of individuals who selected a TVS chit and were asked for TVS to monitor their follicles every other day from day 11 to day 12, or until the follicle ruptured. The cycle was regarded as anovulatory if on day 25 there was no visible dominant follicle. Timed sexual activity was recommended for both groups following a positive urinary LH surge test or the approaching ovulation period on TVS (follicle size about 20±2 mm). Letrozole dosages were sequentially raised in anovulatory cycles, up to a maximum dose of 7.5 mg as required. The primary objectives were to detect ovulation, as evidenced by a positive urine LH test in group 1, and follicular rupture of follicle with fluid in pouch of douglas (POD) on TVS in group 2.

The secondary results were the amount of letrozole required for ovulation, the rate of conception, and the identification of the day of ovulation based on follicular size. For categorical variables, descriptive findings were shown as proportions or percentages; for continuous data, they were shown as mean and standard deviation along with the median and interquartile range. The proportions were compared using the Fisher Exact and Chi-square tests (categorical variables). Continuous variables were examined using the Mann-Whitney test or student t-test (independent group/unpaired data), with $p<0.05$ indicating significance.

3. Results

LH surge kits diagnosed ovulation induction in 78 (54.17%) of the 144 women, and TVS was used in 66 (45.83%) of the women (Table 1). The average age in Group 1 was 26.9 years, while in Group 2, it was 26.85 years (Table 2). The study population had an average BMI of 25.28 kg/m2. With an average marriage length of 5.35 years, most women in both groups were homemaker (81.81% in group 2 and 94.8% in group 1) and nulliparous (87.50% in group 1 and 84.48% in group 2). The LH surge group suffered infertility for 4.32 years, whereas the TVS group had it for 4.7 years (p=0.7743). Primary infertility occurred in 71.79% of group 1 and 72.72% of group 2. The TVS group had somewhat longer menstrual flow duration, but this difference was statistically insignificant (p=0.6049).

Table 1: Sample size distribution

Parameters	N	%
Total sample size of patients	144	100.00
Number with LH surge kits	78	54.17
Number with TVS	66	45.83

The menstrual cycle was lengthier in the TVS group compared to the LH surge kit group (32.48 vs. 30.23 days; p=0.4191). Most of the women studied had normal menstrual flow parameters (p=0.6608). Thirty women in the TVS group experienced more dysmenorrhea than the LH Kits surge group (21.22 vs. 20.52), but the difference was statistically insignificant (p=0.9423). The LH surge kit group had a higher percentage of patients with dyspareunia (10.26) than the TVS group (3.04), although the difference

Table 2: Demographic parameters

Demographic parameters		Overall	LH surge kit group	TVS group	P value
Age related parameters	Mean	26.88	26.90	26.85	0.6947
	SD	4.23	3.76	4.79	
	Median	27.00	27.00	26.00	
	Quartile 1	24.00	25.00	24.00	
	Quartile 3	29.25	29.50	24.00	
BMI related parameters	Mean	25.28	25.57	24.93	0.5597
	SD	3.89	4.33	3.34	
	Median	24.55	24.88	23.90	
	Quartile 1	22.60	22.86	22.60	
	Quartile 3	27.78	27.65	27.70	
Occupation	Housewife	128(88.88)	74(94.87)	54(81.81)	0.0811
	Parlour	2 (1.38)	0	2(3.03)	0.2770
	Tailor	6 (4.16)	2(2.56)	4(6.06)	0.4620
	Teacher	8 (5.55)	2(2.56)	6(9.09)	0.2313
	Total	144	78	66	-
Parity status	Zero/Nulliparous	126(87.50)	70(89.74)	56(84.48)	0.5068
	Parity 1	10 (6.94)	4(5.12)	6(9.09)	0.5119
	Parity 2	6 (4.16)	4(5.12)	2(3.03)	0.6604
	Parity 3	2 (1.38)	0	2(3.03)	0.2770
	Total	144	78	66	-
Duration of marriage (years)	Mean	5.35	5.06	5.68	0.9616
	SD	3.93	2.71	5.03	
	Median	5.00	5.00	5.00	
	Quartile 1	3.00	3.00	3.00	
	Quartile 3	6.00	6.00	7.00	
Duration of infertility (years)	Mean	4.49	4.32	4.70	0.7743
	SD	3.08	2.44	3.73	
	Median	4.00	4.00	3.00	
	Quartile 1	2.00	3.00	2.00	
	Quartile 3	6.00	6.00	6.00	
Status of infertility	Primary	104(72.22)	56(71.79)	48(72.72)	0.9305
	Secondary	40 (27.78)	22(28.21)	18(27.28)	
	Total	144	78	66	

was not statistically significant (p=0.2333). The median letrozole cycle count in this study was one, with a mean of 1.75 (Table 4). While the TVS Group had a higher average number of cycles than in the LH surge kit group (1.91 vs. 1.62; p=0.2642), the median number of cycles was the same in both groups. First cycles account for 57% of instances, with second cycles (19%), third cycles (17%), and fourth cycles (7%), following in order of ovulation. The women in group 1 who received one cycle of letrozole were 61.53% in comparison to 20.51%, who received 2 cycles. Nonetheless, a higher proportion of women in group 2 went through three (24.24%) or more (9.09%) cycles. Even though the results were same in both the groups. In most of the study participants, letrozole dose used was only 2.5 mg for 5 days. In the TVS group (39.40%) women were received a higher dose (5 mg) of letrozole in comparison to LH surge kit group (20.40%) (p=0.0812).

Ac compared to group 2, the average day for detection of ovulation, was shorter for group 1 (16.24 days versus 15.21 days). (Table 5). It has been suggested that the LH surge kit may diagnose ovulation almost a day before than the TVS, difference of which was found to be statistically significant (p = 0.0124). The mean endometrial thickness (ET) on TVS was 8.3 mm.

During the study's follow-up period, 20 patients (13.89%) disclosed being pregnant (Table 6). After

Table 3: Menstrual characteristics

Menstrual characteristics		Overall	LH surge kit group	TVS group	P value
Cycle duration related parameters	Mean	31.26	30.23	32.48	0.4191
	SD	7.63	3.22	10.68	
	Median	30.00	30.00	30.00	
	Quartile 1	30.00	30.00	30.00	
	Quartile 3	30.50	30.00	32.00	
Menstrual flow duration related parameters	Mean	4.82	4.77	4.88	0.6049
	SD	1.76	1.91	1.60	
	Median	4.50	4.00	5.00	
	Quartile 1	4.00	4.00	4.00	
	Quartile 3	5.00	5.00	6.00	
Menstrual flow character	Normal	138(95.83)	74(94.87)	64(96.96)	0.6608
	Heavy	6(4.17)	4(5.13)	2(3.04)	
	Total	144	78	66	
Dysmenorrhea	Absent	114(79.16)	62(79.48)	52(78.78)	0.9423
	Present	30(20.84)	16(20.52)	14(21.22)	
	Total	144	78	66	
Dyspareunia	Absent	134(93.05)	70(89.74)	64 (96.96)	0.2333
	Present	10(6.95)	8(10.26)	2(3.04)	
	Total	144	78	66	

Table 4: Number of letrozole cycles and letrozole dose distribution in the study population

Number of Letrozole cycles	Overall	LH Surge kit group	TVS group	P value
One	82 (56.94)	48(61.53)	34(51.51)	0.3956
Two	26(18.05)	16(20.51)	10(15.15)	0.5585
Three	26(18.05)	10(12.82)	16(24.24)	0.2126
Four	10(6.94)	4(5.12)	6(9.09)	0.5119
Total	144	78	66	-
Mean	1.75	1.62	1.91	0.2642
SD	0.99	0.91	1.07	-
Median	1.00	1.00	1.00	-
Quartile 1	1.00	1.00	1.00	-
Quartile 3	2.25	2.00	3.00	-
Letrozole dose (mg)				
2.5	102(70.83)	62(79.48)	40(60.60)	0.0812
5	42(29.17)	16(20.51)	26(39.40)	
Total	144	78	66	

Table 5: Day of ovulation as per method of diagnosis

Ovulation day	LH Surge kit group	TVS group	P value
Mean	15.21	16.24	0.0124
SD	1.15	2.02	
Median	15.00	16.00	
Quartile 1	14.00	15.00	
Quartile 3	16.00	17.00	

Table 6: Pregnancy based on method of diagnosis and type of infertility

Pregnancy status	LH surge kits	TVS group	Grand total	P value
Primary infertility	56	48	104	
No Pregnancy	50(89.28)	38(79.16)	88	0.3181
Pregnancy	6(11.72)	10(20.83)	16	
Secondary infertility	22	18	40	
No Pregnancy	20(90.90)	16(88.88)	36	0.8840
Pregnancy	2(9.09)	2(11.12)	4	
Grand total	78	66	144	

detecting ovulation, we monitored the women for four cycles to determine the result of pregnancy. Compared to the patients who received an LH surge kit (8, 10.26%), the TVS group of patients (12, 18.19%) had a greater pregnancy rate.

Maximum patients became pregnant during the first cycle (40%) with letrozole dose of 2.5 mg, subsequently in the second cycle (30%) with 2.5 mg letrozole, in the third cycle (20%) with 5 mg letrozole, and in the fourth cycle (10%) with 5 mg letrozole, results of which were found to be statistically insignificant (p=0.3358). The TVS determined that the mean follicular size before or at rupture was 22 x 22 mm. The majority ovulate at follicular size of 20x24 mm (33%), with a minimum size of 16x18 mm (3% cases) and a maximum size of 24x26 mm (12% cases).

4. Discussion

Eighteen to twenty-five percent of women who present with infertility and require ovulation induction have an ovulatory problem. TVS is an invasive method that may sometimes also need a radiologist to document the results and provides a clear definition of ovulation time. But many a times women hesitate for TVS examination. So, a new non-invasive technique for detection of ovulation is the LH surge kits (i.e., LH surge assessment in urine), which a woman can use on her own without a radiologist or special environment. Compared to TVS, these over-the-counter alternatives are readily available and simple to use. One hundred forty-four patients with anovulatory infertility were included in the study. On days 2 or 3, every woman received letrozole (2.5–7.5 mg daily for 5 days) for ovulation induction. Follicular monitoring by TVS or urine LH surge testing were the two procedures used to analyze the subsequent ovulation.

The patients' median age was 27 years, and their average age was 26.88 years. In the survey, the average length of marriage was 5.35 years. The average span of infertility was longer in our study as compared to a similar study carried out in a tertiary care hospital (42 months).[2] The average BMI was 25.28 kg/m2, which is higher than the typical BMI that is advised for Indian ladies. Females who are overweight or obese are more likely to become infertile.[3]

The average menstrual cycle length was 31.26 days, with a SD (standard deviation) of 7.63 days. Letrozole had been chosen for induction over clomiphene citrate because it doesn't appear to have similar detrimental effects on cervical mucus and the endometrial thickness.[6] Letrozole is also considered to be the first treatment option for PCOS and oligo-ovulatory women seeking ovulation induction, irrespective of body mass index (BMI). Letrozole in the 2.5 mg to 7.5 mg dosing range was initially investigated for its ability to induce ovulation. In both study groups, 2.5 mg was the dose that was given most frequently. Compared to the TVS group (60.60%), a larger percentage of patients (79.48%) had a 2.5 mg letrozole dose in the LH surge kit group. The two groups' distributions were comparable because the difference statistically insignificant (p-0.0812).

Using the assessment approach, it was found that the average day of ovulation diagnosis was 15.21 days for group 1 and 16.24 days for group 2. So, it is clearly apparent that, in comparison to the TVS, ovulation was diagnosed approximately one day prior in the LH surge kit group (p = 0.0124), results of which were found to be statistically significant. The results demonstrated that, the total pregnancy rate for both the groups were 13.89%, with comparable results.

In terms of clinical characteristics and demographics, both groups were similar. Previous research has demonstrated comparable outcomes when describing techniques for ovulation detection by urine LH surge rather than ultrasonography due to its high accuracy, low cost, and less invasive nature.[9–11]

5. Conclusion

Since the LH surge kit is a subjective method for ovulation assessment, there is a greater chance of error. However, because it is practical, affordable, non-invasive, and convenient, it can be recommended for patients who live far from the radiologist, cannot afford to travel to the hospital, or are uncomfortable undergoing any kind of invasive procedure. TVS is advised as the standard modality for ovulation detection since it is an objective, more accurate, and error-free means of assessing ovulation. However, it is costly, intrusive, and impractical in isolated places. Therefore, we propose that LH surge kits, as an

alternative to TVS follicular monitoring, can be a useful tool for ovulation assessment.

6. Sources of Funding

None.

7. Conflict of Interest

None.

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