

Pregnancy following use of the cervical cup for home artificial insemination utilizing homologous semen*

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Sixty-one couples with infertility from 1 to 11 years were instructed in the use of the cervical cup for artificial insemination using homologous semen in the privacy of their own homes. There have been 36 reported pregnancies in 32 of these couples. Among women with primary infertility, the pregnancy rate was 43%; it was 67% for those with secondary infertility and 53% overall. Sperm counts and percent motility, as well as postcoital test results, however, failed to be indicative of eventual ability to conceive. Regardless, among couples with documented infertility, this method provided over half of the couples with at least one pregnancy. Additionally, the technique is simple, inexpensive, without significant risk or discomfort, and can be carried out by a couple at their convenience and in privacy.
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Infertility is a discouraging, emotionally depressing reality that affects an estimated 10% to 20% of all couples¹; yet it remains estranged both from public thought and conversation. Infertility can have as its cause female and/or male factors. Causes for female infertility can be characterized as relating to ovulatory, endometrial, tubal, peritoneal, cervical, or mucus factors. Male infertility can result from abnormalities in sperm number, motility, or morphologic characteristics. However, despite thorough investigation, the generation of medical expenses, patient and physician

stress, and potential patient morbidity, the cause of their infertility remains unestablished for some of these couples.

Artificial insemination using homologous (AIH) or donor (AID) semen has been performed in selected couples with male factor problems to increase the pregnancy rate. Various techniques have been suggested, including the "cervical cup," which could be used in the physicians' office² or at home.³ This paper describes our experience with the use of the cervical cup for home AIH among couples with primary or secondary infertility of varying causes.

MATERIALS AND METHODS

Couples were selected from those who presented to the Center for Fertility and Reproductive Research (C-FARR) at Vanderbilt University Medical Center for evaluation of infertility. Primary infertility was defined as the inability to

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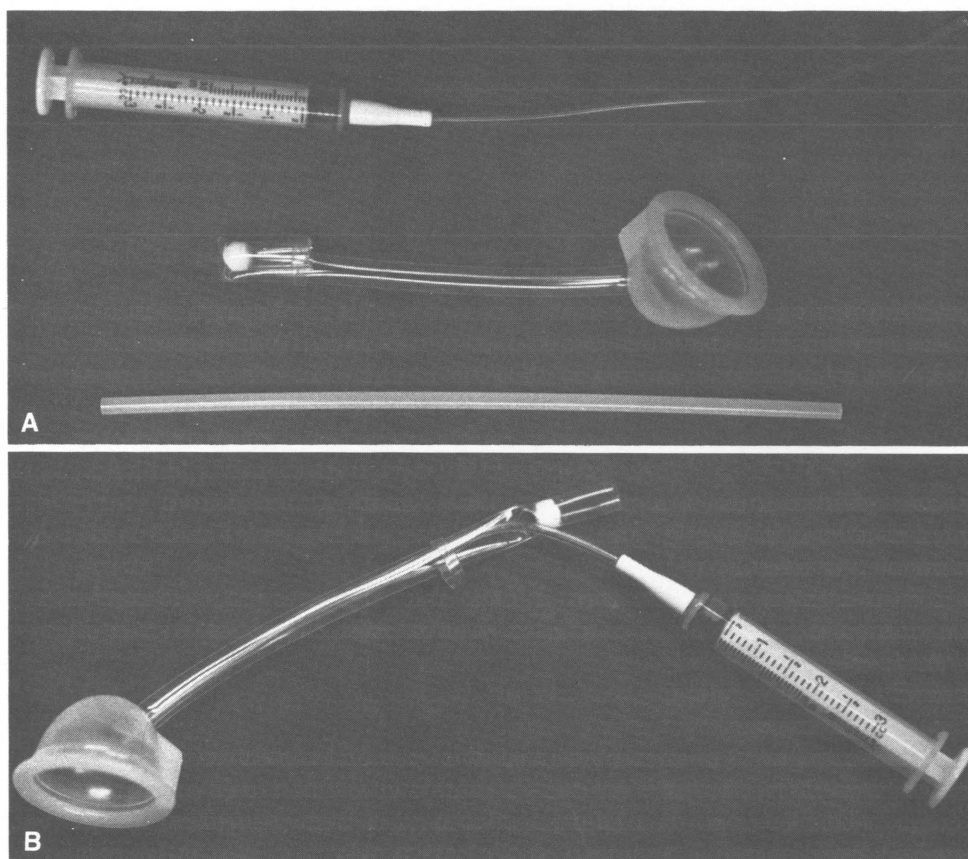


Figure 1
 (A), The cervical cup and syringe for introducing sperm into the cup. The lower structure is an applicator, which advances the white ball in the stem of the cervical cup to prevent loss of semen into the stem. (B), Syringe and tubing shown in the proper position for introducing semen into the cervical cup.

achieve pregnancy over at least a 1-year period in a woman with no prior pregnancies. Secondary infertility was defined as the inability to conceive over the same time period in a woman with at least one prior pregnancy.

The choice of couples to be instructed in home AIH were those who were felt to have a significant male factor problem based on a combination of a repeatedly poor postcoital test (PCT) and/or a subnormal semen analysis. Poor results in the PCT were considered to be less than 2 to 4 sperm in the best field after scanning multiple regions of the slide and/or little or no sperm motility. Good results in the PCT were considered to be greater than 10 sperm per high-power field in numerous fields, with good motility. Improved results in the PCT showed an increase in sperm number in each high-power field and/or an increase in motility.

Couples were considered candidates if the woman had a normal hysterosalpingogram, regular menses with a biphasic basal body temperature (BBT) chart, an in-phase endometrial biopsy, and a normal pelvic examination. Patients in various stages of evaluation for their infertility problem who had either a "suboptimal" semen analysis or

poor PCT results were offered the opportunity to begin a home AIH program while still being investigated for other factors that might affect their infertility. For example, in a couple with poor PCT results and suspected endometriosis, home AIH was offered as an option while the couple debated whether to undergo a diagnostic laparoscopy. Severely oligospermic men with counts less than 5 to 10 million/ml with poor motility were informed that AID would probably be a better option. Instruction in home AIH, once mentioned to a couple, even with poor PCT results and severe oligospermia, was not denied.

Couples were instructed in the office in the proper placement of the correct size of cervical cup. Sperm collection by masturbation using a fractionated (split) sample method was taught, with the first portion of the ejaculate to be used for insemination after verification of the sperm concentration. After waiting 3 to 5 minutes to allow liquefaction, the semen was drawn up through the plastic sheath portion of a 14-gauge angiocath into a syringe. This catheter tip was then inserted into the allotted slot in the stem of the cervical cup (Fig. 1) (Milex Corporation, Chi-

Table 1. *Duration and Type of Infertility*

Years of infertility	Became pregnant		Did not become pregnant	
	Primary infertility	Secondary infertility	Primary infertility	Secondary infertility
1	2	1		
2	1	1		2
	6	6	7	3
	1	1		
3		2	3	1
4	1	1	4	
	1			
5	1	2	3	1
6	2		2	1
	1			
7		1		
8				
9				
10		1		
11			1	
Total	16	16	21	8

chago, IL) which had previously been self-inserted into the vagina onto the cervix. The semen was then slowly introduced into the cervical cup stem. The white ball in the stem of the cervical cup was then advanced toward the cup by pushing it through the stem with an applicator. The cup was then left in place at least 6 hours. Couples were instructed to use the cup 1 to 3 times each cycle during the periovulatory period and to determine the proper timing by monitoring of BBTs, knowledge of cycle length, and self-awareness of cervical mucus changes.

All numeric results are expressed as mean $\pm$ standard deviation.

RESULTS

Of the 61 couples instructed in the use of the cervical cup for home AIH with primary or secondary infertility ranging from 1 to 11 years (Table 1), there have been 36 reported pregnancies in 32 women. Thus, at least one pregnancy occurred in 53% of the couples. There were three spontaneous miscarriages, two in one couple, and no ectopic pregnancies.

Following instruction in home AIH, women with primary infertility who subsequently became pregnant required 3.8 ± 2.0 cycles in order to become pregnant, compared with 4.1 ± 4.0 cycles for women with secondary infertility. Of the 29 couples for whom home AIH has not been successful to date, 16 are still practicing home AIH, 6 chose AID (1 has been successful), 3 chose to adopt children, 1 has been referred for psycho-

logic evaluation, and the choices of 3 are unknown. Among the women with continued infertility, all but six attempted AIH for at least six cycles. Two used AIH for five cycles and two for four cycles, and the remaining two patients were lost to follow-up. It was assumed they did not become pregnant.

The sperm counts and percent motility from the husbands in each group are shown in Figure 2. In cases where more than one determination was performed, the mean is shown. (Results are not available for four men, three of whose wives became pregnant.) The sperm counts and percent motility varied considerably, regardless of whether the couple had primary or secondary infertility, and regardless of whether pregnancy ensued or not.

PCTs were performed both prior to and after home AIH in 38 couples. There was an improvement in the PCT in 30 of these couples; however, only 16 became pregnant (Table 2). Two of the couples who showed no improvement in the PCT also became pregnant.

Known infertility factors among the couples in each group included endometriosis, fibroids, anovulation, "poor" mucus, sperm antibodies, hyperprolactinemia, retrograde ejaculation, and varicocele. None of the women had vaginismus from cup insertion or removal, and no complications were reported by the cup users.

Because of the wide variety of variables and the subsequent small numbers in each group, statistical analysis of the role of the many factors in the subsequent ability to conceive was not performed.

DISCUSSION

Among these 61 couples with documented infertility, 53% were able to achieve pregnancy utilizing the cervical cup for home AIH. These results are in contrast with the lower conception rates often reported for AIH by previous individual reports (Table 3)²⁻¹¹ and reviews.^{9, 12} This discrepancy in results may in part be due to patient selection, inasmuch as some of the husbands

Table 2. *Postcoital Tests*

	Improved	Not improved	Not recorded	Total
Pregnant	16	2	14	32
Not pregnant	14	6	9	29
Total	30	8	23	61

Table 3. *Success of Conception with AIH*

	No. of patients	Patients conceiving using AIH	
		No.	Percentage
Whitelaw ²	32	14	43
Whitelaw ³	82	10	12
Dixon et al. ⁴	158	15	10
Moghissi et al. ⁵	62	9	15
Nunley et al. ⁶	69	11	16
Adoni and Palti ⁷	25	5	20
Pfeffer et al. ⁸	38	12	32
Corson and Batzer ⁹	100	13	13
Speichinger and Mattox ¹⁰	24	1	4
Scott et al. ¹¹	110	23	21
Diamond et al.	61	32	53

in our group had normal sperm morphologic characteristics, counts, and motility, which tend to elevate our success rate. However, as illustrated in Figure 2, sperm count and motility were not accurate means of differentiating which couples would eventually conceive. This finding confirms similar results reported previously by Pfeffer et al.⁸ Another contributing factor to the difference in AIH success rates could be the absence of a control group. While there were no reports of spontaneous pregnancies occurring among our couples during home AIH cycles, others have reported the rate to vary between 6% and 25%,^{4-6, 13-15} with the mean by two recent reviews of 12% to 14%.^{9, 12}

Alternatively, the improvement in the conception rate may be due to the home use of the cervical cup. Whitelaw² initially reported that in couples with infertility of at least 2 years and husbands with sperm counts less than 60 million, 14 of 32 couples achieved a pregnancy through the use of the cervical cup. Subsequent studies, despite this initial success, yielded much poorer results.^{4, 6, 10, 11} However, only Whitelaw³ utilized home AIH, and in this case the severe degree of oligospermia may have greatly contributed to the low success rate.

The improved conception rate with this method of home AIH could be due to the use of "fresh" semen specimens or psychologic factors, as well as the mechanical advantages of this form of cervical cup. These latter advantages include protection of the sperm from a potentially hostile vaginal environment (e.g., acidity)¹⁶; and minimization of semen loss as can occur during introduction of other forms of cervical cups (such as those initially described by Whitelaw²), as well as minimization of subsequent potential leakage of semen away from the cervix and out of the vagina,

as can occur with other insemination techniques. This mechanical advantage is suggested by the improvement in the PCT results in 30 of the 38 women in this study in whom pre- and post-AIH PCTs were performed.

With regard to sample collections for home AIH, the specimen can be obtained immediately prior to insemination when elected by the couple, regardless of the day of the week or the physician's office hours. Furthermore, sperm motility might be maximized by immediate insemination,¹⁷ as contrasted to insemination following transporting of the specimen to the physician's office and potential waiting room delays.^{3, 12}

Psychologic stresses have been implicated as a cause of infertility in men as well as women.^{3, 18, 19} This factor could be either accentuated or introduced by application of AIH with creation of irregular menses in women and production of poorer semen specimens³ or premature ejaculation and impotence in men. These factors might be minimized with home AIH because masturbation can be performed in the privacy of the couple's home without the involvement of the third party. In this way, the couple can regain control of the process and potentially develop increased self-esteem along with it.

Additional advantages of home AIH include minimization of medical expenses as well as sub-

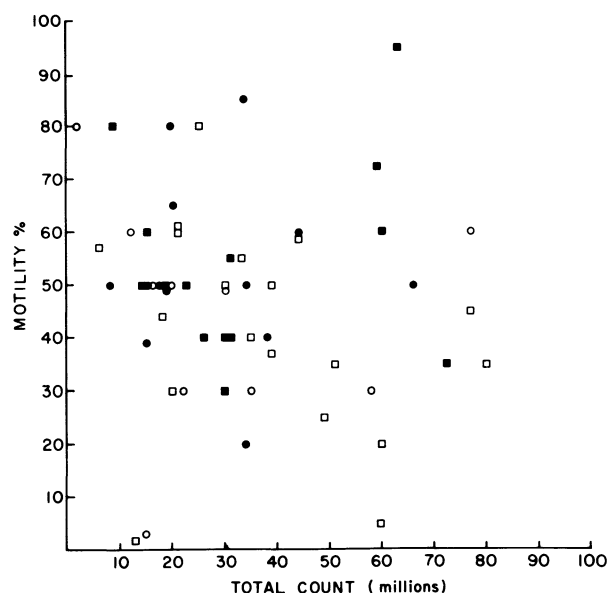


Figure 2
Sperm count and percent motility among husbands of couples who did (solid) and did not (open) achieve pregnancy in women with primary infertility (squares) or secondary infertility (circles).

stantial time savings to both the couple and the physician. Also, the wife could help the husband in the collection of the sample at home and restore a sense of sexuality to the procedure.

There were only 3 miscarriages among the 36 pregnancies reported, 2 in the same couple. In contrast, Nachtigall et al.,¹² in a recent review, reported a mean spontaneous abortion rate of 25% following AIH. The explanation for this difference remains unclear.

Regardless of the mechanism by which it occurred, by using the cervical cup for home AIH, 32 of 61 couples with documented infertility were able to conceive utilizing this method of insemination. Thus, the potential benefit, namely, the generation of a pregnancy, was accomplished in over half of the couples, without any reported morbidity. These results thus represent a substantial improvement over previously reported cervical cup studies as described earlier.

Furthermore, neither the actual sperm count and motility nor the results of the PCT seem to be an adequate indicator of which women will conceive. Under these circumstances, it seems reasonable to allow a trial of home AIH utilizing the cervical cup in all infertile couples excluding those with documented female anatomic abnormalities (e.g., total tubal occlusion). This trial should be continued for six to eight cycles, in view of our experience and the experience of other investigators^{4, 6, 9, 11, 13} that, on the average, four cycles were required to achieve pregnancy.

In an infertile couple with limited financial means, the use of the cervical cup for home AIH could be initiated prior to an extensive (and expensive) medical evaluation. Alternatively, such a trial could be utilized as a "last-ditch effort" when the examination fails to identify a cause for infertility or when a male factor is suggested. Further investigations and more liberal application of this simple, safe, and economical procedure seem indicated.

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