

INTRAUTERINE INSEMINATION TREATMENT IN SUB FERTILITY: ANALYSIS OF FACTORS AFFECTING OUTCOME

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ABSTRACT

Background Intra uterine insemination is an assisted reproductive technique using husband or donor sperm, at the time of ovulation in natural or stimulated cycle put in the uterine cavity or in the cervical canal.

Objective To identify factors that can predict successful outcome in intrauterine insemination.

Methods a prospective study, 193 cycles of intrauterine insemination were analyzed to identify prognostic factors regarding treatment outcome. The variables selected for analysis were: female age, infertility duration and etiology, types of infertility, sperm parameters after preparation (count and progressive motility), number of preovulatory follicles, thickness of endometrium and type of ovarian stimulation. The data were analyzed with chi – square test.

Results The overall pregnancy rate was 7.8%; the miscarriage rate was 60%, and no ectopic pregnancy or multiple pregnancies were encountered. Five significant variables were identified for successful outcome: endometrial thickness (P=0.001), number of treatment cycles (P=0.002), number of preovulatory follicles (P=0.038), progressive motility of sperm after preparation (P=0.05), and female age (P=0.05).

Conclusion intrauterine insemination should be considered prior to more invasive and expensive other assisted reproductive techniques as in vitro fertilization and gamete intra-Fallopian transfer. Careful couple's selection is a crucial factor in enhancing conception with this method.

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Key words: IUI, Infertility, ART

Intrauterine insemination (IUI) is one of assisted conception techniques in which a sample of washed, prepared motile sperm is deposited in the uterus at the time of ovulation in a natural or stimulated cycle.¹ IUI is a form of therapeutic insemination (TI) using the husband's (AIH) or donor (AID) sperms. IUI has a significant cost saving and less invasive compared with other forms of assisted reproductive techniques such as in vitro fertilization (IVF) or gamete intra-Fallopian transfer (GIFT).²

Controlled ovarian stimulation (COS), with IUI has been another important factor to the increased use of IUI treatment. It

was first described by Sher et al.³

The indications of IUI are: nonsevere male factor infertility, unexplained infertility, cervical mucus hostility, ovulatory disturbance, and for some couples with immunologic abnormalities.^{3,4} The male factors which benefit from using IUI with Controlled ovarian hyperstimulation COH⁵ are: decreased sperm motility $\geq 30\%$ ⁶ and decreased sperm quality, disorders of sperm function, defects of the penis, and other form of ejaculatory dysfunction as spinal cord injury patients.⁷

Female factors that may benefit from IUI are: Scant or unreceptive mucus, persistent cervicitis, and cervical

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stenosis.^{7,8} IUI with superovulation is favored as the treatment of choice for unexplained subfertility.⁹

There was a trend toward an increased success rate with increased total motile sperm count > 5 million.^{10,11} According to the World Health Organization (WHO) Manual criteria: motility is graded from a to d, as follows: Grade (a) sperm are those that swim forward fast in a straight line, Grade (b) sperm swim forward, but either in a curved or crooked line, or slowly. Grade (c) sperm move their tails, but do not move forward and Grade (d) sperm do not move at all. WHO previously accepted 30% as normal, Kruger et al (1986) have described 'strict criteria' where less than 14% normal morphology would indicate the need for assisted conception.^{6,12,13} The live birth rate per insemination declines with advancing age. IUI is useful for cervical mucus hostility, cervical infection, or the presence of antisperm antibodies.¹⁴

The main contraindications to IUI are: the presence of persistently less than 5 million motile sperms.¹⁵ and pelvic inflammatory disease as the incidence of ectopic pregnancy is about 1 in 6. Other complications include bleeding, uterine cramping, infectious and allergic reactions.^{1,16,17}

There are currently many different hormonal treatment protocols for COH combined with IUI. The use of clomiphene and Gonadotrophins is to induce COH.^{7,18,19}

Success rates are in the region of 5 - 30%,²⁰⁻²⁴ and depend upon many factors including: cause of infertility as IUI is of more value for infertility caused by male and cervical factors. The quantity and quality of sperms produced are important.²⁵ Also it's stated that sperm DNA quality may predict IUI outcome and that the stability of the sperm DNA status is a parameter for positive outcome, while the extent of its fragmentation is an indicator of poor IUI outcome.³ Women with healthy Fallopian tubes and who ovulate regularly have a higher chance of

achieving pregnancy than those whose tubes are not healthy or do not ovulate regularly.²⁴ The younger the woman the higher the chance of conception.²⁵ The chance of conception declines with the longer period of infertility.^{26,27} It is generally accepted that re-evaluation and discussion about other forms of treatment such as IVF and GIFT should be carried out with the couples after 6 consecutive failed cycles.^{11,27-29}

PATIENTS AND METHODS

In this prospective study, evaluation of 223 IUI cycles was done for 170 couples. All cycles were carried out between March 2004 and December 2004 at the infertility clinic of Al - Batool Maternity Teaching Hospital in Mosul city.

The studied couples had at least one year of infertility, or less than this period if there were already identifiable risk factors such as female age above 35 years or known male factor for infertility. The enrolled had a basic infertility evaluation as semen analysis for the male partner, hormonal assay (FSH, LH, serum prolactin, serum testosterone, thyroid function test, and mid luteal serum progesterone), transvaginal ultrasound to assess ovulation and structural normality of the female genital organ. Tubal patency was investigated by laparoscopy or hysterosalpingography and all women with tubal abnormalities were excluded from the study. If pregnancy was not achieved after two to three ovarian stimulation/IUI cycles, tubal patency was re-evaluated and 5 cycles were excluded.

Another 25 cycles were excluded from the study because they didn't return to the clinic after performing IUI, which made the total number of the cycles 193.

The mean female age was 31.3 (range 18 - 47) years and the mean duration of infertility was 6.96 (range 1 - 25) years.

Women in the study had transvaginal ultrasound performed on the second day of the menstrual cycle as a baseline, and then

underwent ovarian stimulation. The first group used clomiphene citrate alone, 100 - 200 mg on day 2 - 6 of the cycle. The second group where those who didn't respond to clomiphene citrate alone, human menopausal gonadotrophins (HMG)/gonalf Serono were added, started on day 5, 1 - 2 ampoules/day until the follicle reached the acceptable size. The third group were women who didn't respond to the above two regimes, and HMG alone used with standard set up method. Sometimes IUI was performed on natural cycles when the women attended the clinic at the time of mid cycle, and discovered to have one or more mature follicles.

Ovarian and endometrial response were monitored by transvaginal ultrasound on cycle day's 9 - 13 (every 2 - 3 days after HMG injection), and 10000 I.U of hCG (pregnyl) was administered when at least one follicle was more than 16mm in mean diameter and endometrial thickness of 8 - 10 mm. Standard IUI was performed at approximately 36 hours after administration of hCG.

Semen was collected by masturbation into a sterile jar or condom after 2 - 4 days of sexual abstinence. After liquefaction and initial sperm analysis, the standard swim up technique was used for preparation, employing Medi - cult medium supplemented with human serum albumin and no antibiotic was added. The sperm sample was centrifuged at 500g for 15 minutes. The supernatant was discarded and the pellet diluted in 2.5 ml of medium and recentrifuged. After removing the supernatant the final pellet was gently covered with medium and incubated for one hour at 37°C in an incubator.

IUI was performed using an intrauterine catheter with 1 ml syringe. The catheter was gently passed through the cervical canal and the sperm suspension expelled into the uterine cavity. Insemination volumes ranged from 0.5 - 1 ml. The woman remained supine for 10 - 15 minutes after IUI. If menstruation was

delayed, a serum hCG test was performed 10 days after a missed period. All pregnancies were confirmed by ultrasonography.

A chi-square test was used to identify significant variables that contribute to the success of ovarian stimulation / IUI treatment, and to predict the probability of pregnancy for each treatment cycle. The variables selected for the initial analysis were female age, duration of infertility, type and diagnosis of infertility, sperm concentration and progressive motility (grade a+b) after preparation, number of preovulatory follicles (> 16 mm in diameter), thickness of endometrium, number of the treatment cycles and drug used for ovarian stimulation.

Female age was treated as dichotomous variable: <40 or ≥ 40 years and duration of infertility as <6 or ≥6 years. The categories of sperm concentration were <5×10⁶, 5 - 10×10⁶ or > 10×10⁶ and progressive motility (grade a+b) of <40% or ≥ 40%. The number of follicles and treatment cycles were categorized as follows: 1, 2, 3 or 4 (more than 4 follicles were recorded as 4) and 1,2,3,4 or 5 cycles (more than 5 cycles was recorded as 5) respectively. The thickness of the endometrium was also treated as categorical variables, <6, 6 - 10, or >10 mm. The chosen level of significance was $p < 0.05$.

RESULTS

A total of 193 cycles were analyzed. The overall pregnancy rate per cycle was 7.8% (15/193). Of the 15 pregnancies, 6 (40%) were viable, 9 (60%) resulted in miscarriages, all the pregnancies were in different couples so we can say results were per couples. There was no ectopic pregnancy or multiple pregnancies. Pregnancy outcome is presented in table 1.

Table 2 summarized the pregnancy rate according to the female characteristics. Couples with combined factors were excluded from the study. The

pregnancy rate in women <40 years was significantly higher than in older women (9.6% versus 0 %), although the difference was statistically not significant ($p=0.05$). The pregnancy rate in women with duration of infertility of 6 years or less was higher than those with duration of more than 6 years (9.2% versus 6.0%) but was statistically insignificant ($p=0.407$). Regarding infertility etiology, highest pregnancy rate was achieved in those with ovarian dysfunction (9.1%), followed by unexplained infertility (7.9%), and male factor (6.9%). No pregnancy was obtained in those with endometriosis. However the difference was statistically insignificant ($p=0.935$). Higher pregnancy rate was demonstrated among those with secondary infertility when compared to primary infertility (11.3% versus 6.4%) the difference was statistically not significant ($p=0.257$). Three cases of primary infertility had term pregnancies with living child, and 6 had miscarriages. Three cases with

secondary infertility went into spontaneous labor at term and 3 had miscarriages.

Intrauterine insemination pregnancy rate according to sperm parameters is shown in table 3. The highest pregnancy rate was achieved among couple with sperm count more than 10 million (8.7%), followed by those with sperm count between 5 – 10 million (6.7%), while no pregnancy was observed in those with sperm count of less than 5 million. However the difference was statistically not significant ($p=0.688$). There was statistically significant difference ($p=0.047$) in pregnancy rate among couple in whom progressive motility of sperm after preparation was $\geq 40\%$ as compared to those with $<40\%$ (10.2% versus 1.8%).

The pregnancy rate according to numbers of follicles were (19 %), (14.3%), (7.7%) and (2.5%) with four or more, 3, 2, and 1 preovulatory follicles respectively, the difference was statistically significant ($p=0.038$) as shown in table 4.

Table 1. Pregnancy outcome of the intrauterine insemination cycles

<i>Pregnancy outcome</i>	<i>No. of patients</i>	<i>No. from total</i>	<i>%from total</i>
Pregnancy cycle	15	15/193	7.8
Live births /cycle	6	6/193	3.1
Miscarriages/cycle	9	9/193	4.7

Table 2. Intrauterine insemination and pregnancy rate according to female characteristics

Female character	Pregnancy/cycles	Percent rate	% total	P-value
Age (years)				
<40	15/156	9.16%	7.8	0.050
≥ 40	0/37	0%	0	
Infertility duration (years)				
≤ 6	10/109	9.17%	5	0.407
>6	5/84	5.95%	2.6	
Infertility etiology				
Unexplained	3/38	7.89%	1.6	0.935
Male factor	6/87	6.89%	3	
Endometriosis	0/2	0%	0	
Ovarian dysfunction	6/66	9.09%	3	
Types of infertility				
Primary	9/140	6.4%	4.7	0.257
Secondary	6/53	11.3%	3	

Table 5 demonstrates IUI pregnancy rate according to endometrial thickness. The highest pregnancy rate was observed among those with endometrial thickness of >10 mm time of insemination (50%), followed by those with thickness between 6-10 mm (4.5%), while no pregnancy was observed among those with endometrial thickness <6mm. The finding was statistically significant (p=0.001).

The relation of numbers of treatment cycles with pregnancy rate are demonstrated in table 6. The rate were (33.3%), (28.6%), (9.5%) and (3.9%) with

treatment cycle 4, 3, 2 and 1, there was no pregnancy when the number were ≥ 5 cycles, a statistically significant variable (p=0.002) was found.

Highest pregnancy rate was observed in those receiving both clomiphene citrate and human menopausal gonadotrophins for ovarian stimulation (20%), HMG alone (8.6%) and CC alone (5.2%) each as shown in table 7. No pregnancy was observed in those who underwent IUI on spontaneous cycle. The difference between these variables were statistically not significant (p=0.101).

Table 3. Intrauterine insemination pregnancy rate according to sperm parameters (after preparation)

Sperm parameters	Pregnancy/cycles	Percent rate	% total	P-value
Sperm count($\times 10^6$/ml)				
<5	0/6	0%	0	0.688
5-10	4/60	6.7%	2	
>10	11/127	8.7%	5.7	
Progressive motility:				
<40%	1/56	1.8%	0.5	0.047
$\geq 40\%$	14/137	10.2%	7	

Table 4. Intrauterine insemination pregnancy rate according to number of preovulatory follicles

Number of follicles (≥ 16 mm)	Pregnancy/cycles	Percent rate	% total	P-value
1	2/79	2.5%	1	0.038
2	5/65	7.7%	2.6	
3	4/28	14.3%	2	
≥ 4	4/21	19.0%	2	

Table 5. Intrauterine insemination pregnancy rate according to endometrial thickness

Thickness of endometrium (mm)	Pregnancy/cycles	Percent rate	% total	P-value
<6	0/2	0%	0	0.001
6-10	8/177	4.5%	4	
>10	7/14	50%	3.6	

Table 6. Intrauterine insemination pregnancy rate according to the number of treatment cycle

Number of treatment cycle	Pregnancy/cycles	Percent rate	% total	P-value
1	5/127	3.9%	2.6	0.02
2	4/42	9.5%	2	
3	4/14	28.6%	2	
4	2/6	33.3	1	
≥ 5	0/4	0%	0	

Table 7. Intrauterine insemination pregnancy rate according to drugs used for ovarian stimulation

Drug used for ovarian stimulation	Pregnancy/cycles	Percent rate	% total	P-value
CC (group1)	4/77	5.2%	2	
HMG (group2)	7/81	8.6%	3.6	
Both (group3)	4/20	20%	2	0.101
Spontaneous	0/15	0%	0	

DISCUSSION

The aim of the current study is to uncover prognostic factors for successful outcome in IUI treatment in our practice. Five significant variables were identified. They were endometrial thickness, number of treatment cycles, number of preovulatory follicles, progressive motility of sperm after preparation and the female age.

The overall pregnancy rate per cycle was 7.8%. The success rate of IUI varies considerably between infertility clinics, and the same clinic between different couples. Success rate are in the region of 5-30 %.²⁴ The relatively low success rates in this study explained by the limited facilities of the center due to the condition of the country, the media used for sperm preparation, and irregular availability of drugs used for ovulation induction, especially HMG.

The spontaneous abortion rate in this study was 60 % (9/15), while the live birth rate was 40 % (6/15). There were no cases of multiple pregnancies. This may be due to the relatively small numbers of those who achieved pregnancy which did not provide a reflection of the entire possible outcome and the fear of ovarian hyperstimulation syndrome that made the gynecologists abandon the cycles with more than four follicles.

The pregnancy rate in younger women (<40 years) was significantly higher than in older women (\geq 40 years) , this result was similar to many previous studies. Both Stone et al²⁶ and Rojanasakul et al.²⁷ in their studies found that the success rate appeared to be higher in the younger age groups. The age related decline in female

fecundity has been suggested to be a result of reduced uterine receptivity, and/or decreased oocytes quality.³

The pregnancy rate was higher for those with shorter duration of infertility (< 6) years, but the difference was statistically not significant. The impact of the duration of infertility on the success of IUI varied between studies. Nuojua - Huttunen et al³ found that the duration of infertility is a prognostic factor for live birth among untreated subfertile couples. Also Iberico et al²⁹ found that homologous IUI achieved the best results with infertility duration <3 years. Thus IUI cannot be recommended to patients with a long standing duration of infertility.

The lowest pregnancy rate was observed with endometriosis (0%) inspite of very small number of patient. Nuojua Hutunen et al.³ found a significantly lower pregnancy rate in endometriotic patients. The causal relationship between reduced fertility and endometriosis without tubal involvement is not clear. Extensive investigations suggest a multifactorial etiology for endometriosis associated infertility, which includes, for example, an altered follicular environment, impaired oocytes quality and reduced implantation rate. Immunological alterations observed in women with endometriosis are also thought to interfere with fertility via a direct cytotoxic effect on the gametes and the embryo.³

For other causes of infertility, the results varied between studies, Rojanasakul et al²⁷ found that the success rate appeared to be higher in unexplained infertility.

In this study, the difference between

infertility etiologies in relation to the success of IUI was statistically not significant. Higher pregnancy rate was observed in those with secondary infertility than primary infertility. A result was in agreement with the result reported by Rojanasakul et al.²⁷

Higher pregnancy rate was observed in those with higher sperm count but what is more important than the sperm count, was the sperm motility. This was also demonstrated in other studies. Pasqualotto et al³⁰ found that the percentage of post wash sperm motility, and not the post wash total motile sperm count, can predict successful IUI outcome.

In this study, progressive motility of sperm after preparation was a good predictor of successful IUI outcome, which was in agreement with many studies in this subject. Tomilson et al³¹ found that progressive motility of sperm was one of the predictive variables of IUI success. Tsai et al²³ found that the post prepared sperm motility was the only parameter predicting the successful rate of IUI. This was also found by Shulman et al²⁵ who reported that the degree of sperm motility after appropriate preparation for IUI is the only parameter to be correlated with treatment outcome.

The number of follicles was a prognostic variable for successful IUI outcome. In this regard, a significantly higher pregnancy rate seen in cycles with four or more preovulatory follicles, this being remarkably higher than in cycles with only one follicle. This result was in agreement with the result of other studies. Khalil et al¹⁵ reported that the number of mature follicles at the time of insemination was positively and significantly related to a successful outcome of IUI, however, with an unacceptable high rate of multiple pregnancies with more than 4 mature follicles. Also Iberico et al²⁹ in their study reported that the number of preovulatory follicles was a significant predictor of pregnancy. Multifollicular development may result in an increased number of

fertilizable oocytes and a better quality endometrium and luteal phase, thereby improving fertilization and implantation rates.³ The poor outcomes in cycles with only one preovulatory follicle indicate the necessity of using ovarian stimulation in combination with IUI.³

The current study also showed that highest pregnancy rate was observed among those with endometrial thickness > 10mm which was statistically significant variable that can predict successful IUI outcome, this result is in line with the result of other studies including those of Tomlinson et al³¹ who found that the endometrial thickness was a predictive of IUI success. Also Wang et al demonstrated that the pregnancy rates were statistically correlated with endometrial thickness at the day of hCG injection. Zollner et al³² used three dimensional ultrasound to measure endometrial volume and found that an endometrial volume <2ml at the day of insemination is associated with a poor likelihood of pregnancy. They suggested that the endometrial volume predict endometrial receptivity. However, other studies did not show endometrial thickness as a significant factor for successful IUI outcome.³³

A significant higher pregnancy rate was observed in the fourth treatment cycle in the current study. This is in contrast to the finding of Khalil et al¹⁵ who demonstrated that the first treatment cycle compared to the following up to six treatment cycle was associated with highest pregnancy. Duran et al³ in his study also found highest pregnancy rate in the first treatment cycle and thereafter it remained constant up to the fourth cycle. The result may be explained by small number of patients who had four cycles. However it has been demonstrated that fecundity has been shown to be relatively constant for the first three to seven cycles and that most of pregnancies occur within the first four treatment cycles, favoring a maximum of four IUI cycles before IVF.^{3,34}

Highest pregnancy rate was observed among those who received both CC-HMG which is inconsistent with previous studies.¹⁵

CONCLUSION

IUI is an option for many couples prior to considering more complicated and expensive assisted reproductive techniques such as IVF, and that factors including endometrial thickness, number of treatment cycle, number of preovulatory follicle, progressive motility of sperm after preparation and female age, can predict IUI success, thus careful patient selection criteria combined with ovarian stimulation is the model for IUI success.

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پوخته

Intrauterine insemination وهك ريكهك بو چارهسهریا نهزوكيی

پیشهکی: Intrauterine insemination ئیکه ژ ریکین دهینه ب کارئینان ژ بو چارهسهریا نهزوكيی ب ریکا کارئینانا توومی نیرینه ژ زهلامی یان ژ کهسهکی خوبهخش و دانا ئاڤا زهلامی دناف منداللدانی دا یان گهردهنا منداللدانی دا ل دهمی (ovulation).

نارمانج: دیارکونا فاکتهرین گریډای ب سهرکهفتنا ئهجامین چارهسهریا نهزوكيی ب ریکا (Intrauterine insemination).

ریکا فهکولینی: فهکولینهکا (prospective) هاته کرن. 193 خول ژ Intrauterine insemination هاتنه شلوفهکرن. ئه و فاکتهرین کریډای ب ئهجامین باش بیین چارهسهری هاتنه دهست نیشان کرن و ئه وژی ئهفه بوون: ژیی ئافره تی، میژوو و ئه گهری نهزوكيی، ژمارا کیسولین پیش (ovulation)، ستویراتیا پهردا دناف منداللدانی دا، و جوری وریاکرنا هیلکه دانی. شلوفهکرن ئهجاما یا ئامارا هاته کرن ب ریکا (Chi-square).

ئهجام: ریژا زگریی دناف ئافره تا دا 7.8% بوو. ریژا بهرچوونا بچویکی 60% بوو و چی ژ وان زکیربوون ل دهرفه ی منداللدانی دا یان دوگیان بن ب جمکا. سهرکهفتنا چارهسهری یا کریډای بوو ب ستویراتیا پهردا دناف منداللدانی دا (p = 0.001)، ژمارا خولین چارهسهری (p = 0.002)، ژمارا کیسولین پیش (ovulation) (p = 0.38)، لقینا توومی نیرینه (p = 0.05) و ژیی ئافره تی (p = 0.05).

دهرئهجام: Intrauterine insemination دفتت بهیته بهرجاف وهرگرتن بو چارهسهریا نهزوكيی پیش ریکین دی بیین گرانتر و ب زهحمهت تر وهك in vitro fertilization یان gamete intra-Fallopian transfer. دهسنیشانکرن دروسهت یا هه فزینا بو چارهسهری فاکتهرهکی گرنکه ژ بو زنده بوونا ریژا زگریی.

الخلاصة

التلقيح الاصطناعي كعلاج لنقص الخصوبة: تحليل العوامل التي تؤثر على النتائج

الخلفية: التلقيح الاصطناعي هي احدى طرق تقنيات الخصوبة باستعمال السائل المنوي من الزوج او من متبرع, بعد اجراء بعض المعاملات عليه وحقن السائل داخل الرحم او عنق الرحم في فترة الاباضة.

الهدف: ايجاد العوامل المساعدة لانجاح النتائج في حالات التلقيح الاصطناعي داخل الرحم.

الطرق: دراسة مستقبلية ل193 دورة تلقيح داخلي, حيث تم تحليلها لايجاد الطرق الافضل لتحسين النتائج. العوامل التي اخذت بنظر الاعتبار كانت: عمر الزوجة, مدة وسبب العقم, نوع العقم, ومواصفات السائل المنوي بعد التحضير, عدد البويضات الناضجة, ثخن بطانة الرحم ونوع الادوية المنشطة المستعملة. تم تحليل النتائج باستخدام (Chi-square test).

النتائج: كان معدل حدوث الحمل 7.77%, نسبة الاجهاض عند الحوامل كان 60%, لم تحدث حالة حمل خارج الرحم ولا حالة حمل متعدد. لوحظ وجود خمسة مؤثرات مفيدة على النتائج وكانت: ثخن بطانة الرحم ($P=0.001$), عدد الدورات التي تم التلقيح فيها ($P=0.002$), عدد البويضات الناضجة قبل التلقيح ($P=0.038$), نشاط الحيامن بعد عملية التنشيط ($P=0.05$) واخيرا عمر الزوجة ($P=0.05$).

الاستنتاج: الاستعانة بالتلقيح الاصطناعي في حالات العقم قبل اللجوء الى العمليات الاخرى لتقنيات الخصوبة مثل عملية اطفال الانابيب. ونسبة النجاح تعتمد على الاختيار الامثل للزوجين.