DuoFertility ovulation prediction system to aid natural conception

SUMMARY

DuoFertility is a non-invasive system that monitors a woman’s basal body temperature to determine the time of ovulation. It is designed for home use by couples having difficulty in conceiving where no cause has been identified. Unlike other temperature-based systems where readings are taken once a day, this device continuously measures a woman’s temperature, using a skin patch sensor worn under her arm. This information, together with information about her sleep/wake cycle, is transmitted wirelessly for analysis. The system helps to identify the most likely fertile days in each cycle - around ovulation.

BACKGROUND

Infertility is a failure to conceive after regular unprotected sexual intercourse for two years in the absence of known reproductive pathology. It affects approximately 17% of couples, and although treatments are available where a possible cause can be identified, around 25% of cases are classed as ‘unexplained infertility’ (no cause identified). Infertility can have a significant impact on wellbeing and quality of life. Treatment options for unexplained infertility include tubal flushing, hormonal and drug treatments, artificial insemination (intrauterine insemination, IUI), and in vitro fertilisation (IVF). According to the National Institute for Health and Clinical Excellence (NICE), a typical primary care trust (PCT) or health board may expect to see around 92 new consultant referrals (couples) per 100,000 of population per year. Around 1.5% of babies born in the UK are conceived using assisted reproduction.
CURRENT PRACTICE

Women who wish to increase their chance of pregnancy may try and identify the time of ovulation, when their fertility is highest. A reliable sign of ovulation is an increase in vaginal discharge, which changes from white, creamy or non-existent to clear, stretchy and slippery\(^4\). Other common signs include breast tenderness, bloating, mild abdominal pain, slightly increased body temperature, and increased sex drive\(^4\). Home-use ovulation prediction kits can be bought over the counter, which test the hormone levels in urine to identify the most fertile days in the cycle\(^4\).

An alternative self-testing method is for the woman to measure her basal body temperature (BBT), either orally or in the rectum or vagina once a day upon waking. This can indicate retrospectively when ovulation took place each cycle and may provide information on general ovulation patterns. Several temperature measuring devices designed for this purpose can be bought over the counter or online. However, NICE does not recommend the use of BBT charting as it does not reliably predict ovulation\(^3\).

Expert advice is that to have the best chance of getting pregnant, couples should have sex every 2-3 days throughout the month, every month\(^5\). Although the most fertile days are around ovulation, couples do not need to time having sex to coincide with it provided that they consistently comply with this advice about their frequency of intercourse\(^5,6\). According to expert advice, trying to plan sex around the time of ovulation can cause stress, and this in turn can reduce sex drive and affect the chances of getting pregnant\(^5\).

NEW TECHNOLOGY

DuoFertility from Cambridge Temperature Concepts Ltd is a non-invasive, home-use device for determining the time of ovulation, supported by an online specialist supervisory service. A sensor skin patch is worn continuously by the woman under her arm, and collects thousands of body temperature measurements each day, together with data on the woman’s general body movement and rate of heat loss from the skin into the environment. These measurements are intended to pinpoint and measure BBT when the woman is in deep sleep (i.e. she is at complete rest and thermally equilibrated). It thus provides a more complex version of the traditional BBT measurement method (which takes a single temperature measurement once a day upon waking).

The data are transmitted wirelessly to a handheld reader on which the woman can see her fertility status displayed. She forwards these data along with optional additional information (e.g. about vaginal discharge quality and luteinising hormone [LH] test results) every few days via the internet to the company’s analysis centre, where they are reviewed and interpreted by specialists who, the company claim, can provide more detailed predictions about when ovulation takes place (communicated remotely).

DuoFertility is CE marked and available for consumer purchase in the UK, retailing at £495 with a money-back guarantee if pregnancy is not achieved after 12 months of correct use. Over 1,000 units have been sold to date. DuoFertility is not currently available on the NHS. The company claim that DuoFertility better measures BBT and therefore better determines the time of ovulation, and suggest that this may lead to an increase the rate of natural conception.
CLINICAL STUDIES AND RESEARCH QUESTIONS

A retrospective UK cohort study looked at the pregnancy rate amongst 99 couples using DuoFertility for six months. This sample group was comprised of couples who were eligible for or had undergone IVF or Intra Cytoplasmic Sperm Injection (ICSI) treatment, in which the woman had at least one functioning fallopian tube and menstruated at least six times a year, and the man had a sperm count of greater than five million per ml of ejaculate. The average patient-reported pregnancy rate (i.e. delayed period and positive pregnancy test result) achieved using DuoFertility for six months (a total of 476 cycles amongst the 99 couples) was 19.5% (95% confidence interval 10.3-27.8%). The number of these pregnancies that went on to achieve a live birth (live birth rate or 'pregnancy success rate') was not reported. According to the company, this study has been extended and further data on 242 women using DuoFertility for twelve months are expected to be published soon.

Further research studies are ongoing. A UK observational study of around 30 couples is comparing the performance of DuoFertility with two other fertility monitoring products, the LadyComp/Babycomp monitor (measuring BBT once a day) and the Clearblue Ovulation test (a urine-based hormone test). Another small UK observational study of ten women is looking at the use of ancillary skin temperature (measured using DuoFertility) as a marker of ovulation.

In terms of future research, it would be relevant to know how many couples eligible for IVF in the UK get pregnant spontaneously whilst they are waiting for treatment. Very little data are available on this, although a systematic review of evidence has suggested that the clinical pregnancy rate may be around 12% (and the live birth rate 4%) studies that compare the live birth rate for couples using DuoFertility, with other home-based prediction methods, and with no monitoring at all in this patient group are necessary to determine what health outcome benefits DuoFertility may offer.

Company update on trials - July 2012

A trial of DuoFertility is being planned by NHS North Lancashire with a view to providing DuoFertility to patients prior to IVF treatment. It is due to start in October 2012.

POTENTIAL IMPACT

Infertility services and their provision is currently an area of interest to commissioners with Governmental Policy guidance being issued in January 2010\(^\text{13}\) and updated in a letter to Primary Care Trust commissioners in January 2011\(^\text{14}\).

If it were shown to be effective in increasing the chances of a live birth, the potential benefits of DuoFertility would have to be set against the cost to the individual of purchasing the system over the counter. As current NICE guidelines do not recommend BBT measurement to predict ovulation the potential for use of DuoFertility in the NHS, and therefore its potential impact upon healthcare services and resources, is difficult to estimate.

Lay summary

*Duofertility* is a new medical device for helping women who are having problems getting pregnant. We know that a woman’s temperature may go up a little after she releases an egg (ovulation) and this is the time when she is most likely to become pregnant. *Duofertility* helps a woman keep track of her temperature so that she has a better idea of when ovulation has taken place. Instead of taking her temperature a few times a day with a normal thermometer, this new device uses a special patch worn under the arm to collect temperature readings many times during the day and night. It sends the readings to a handheld device which shows them on a display so that the time of a ‘spike’ in temperature can be seen. The temperatures, together with other information about the woman, can also be sent to the company’s website for their specialists to help her choose the right time to try and get pregnant.

Studies so far show that measuring temperatures is not one of the best ways to improve the chance of getting pregnant, and so many more studies of this new way of measuring temperature will be needed to help the NHS decide whether to use it.

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