

A practical guide to hormonal and heat-based male contraception techniques

J.-C. Soufir · R. Mieusset

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Introduction

New contraception methods for men include male hormonal contraception (MHC) and male thermal contraception (MTC). Both methods, MHC and MTC, have been tested for their inhibiting effect on spermatogenesis, their contraceptive effect and reversibility. Considering that the current data are sufficient to ensure day-to-day contraception, we found it necessary to create a practical guide to both methods that will allow physicians faced with questions regarding male contraception to provide answers and have the tools needed to apply these methods and ensure follow-up at their disposal.

MHC in nine questions (J.-C. Soufir)

For which men does MHC seem acceptable?

Men (under 45 years old) living with a stable partner and accepting that their partner (under 40 years old) is informed of their wish.

- Such men should present strong motivation determined by the following reasons:

J.-C. Soufir (*)

Hisotlogy and embryology service,
Biological reproduction/CECOS, Cassini pavillion, Cohn
hospital, 123, boulevard de Port-Royal,
F-75014 Paris, France
e-mail : jean-claude.soufir@svp.aphp.fr

R. Mieusset (*)

Centre for male infertility, CHU–Paule-de-Viguier hospital,
330, avenue Grande-Bretagne, TSA 70034,
F-31059 Toulouse cedex 09, France
e-mail : mieusset.r@chu-toulouse.fr

- preserving the health of their female partner (medical contraindication to or adverse effects of female contraception methods);
- the wish to balance contraceptive responsibility within the couple;
- In our experience, among 30 couples who have observed MHC as a contraception method:
 - in one third of the cases, the woman had suffered from genital infections after an intrauterine device had been placed;
 - in one third of the cases, the “pills” had caused metrorrhagia, hyperlipidemia or mastodynia;
 - in the remaining third of the cases, the man wished to share the contraceptive responsibility.

Which clinical and biological assessments should be required from a man wishing to use MHC?

What are the contraindications to MHC?

Oral examination:

- Age: the man must be younger than 45 years old. Beyond that age, a vasectomy with sperm conservation is offered;
- Medical history: the treatment is contraindicated in the following cases:
 - history of phlebitis or coagulation disorders;
 - heart diseases, liver diseases (obstructive jaundice, steatosis), kidney diseases (kidney failure), neurological diseases (epilepsy...), respiratory diseases (sleep apnea), psychiatric diseases (psychosis, hyper-aggressiveness), dermatological diseases (acne), prostatic diseases;
- Family history: prostate cancer (one first-degree relative — father, brother — or two second-degree relatives);
- Additionally, the man must not:
 - present tobacco intoxication (over 5cg/day) or alcohol intoxication;

- be treated with medications that alter androgen transport or countering their peripheral action.

During the clinical exam, he must not specifically present:

- obesity (BMI > 30)
- HBP (systolic > 150, diastolic > 9)
- acne.

The following *biological assessment* must be normal: complete blood count, HDL and LDL cholesterol, triglycerides, liver function tests (bilirubin, alkaline phosphatases, ASAT, ALAT, GGT).

Lastly, the *sperm* must be considered fertilising (sperm count higher than 15 million/ml, motility (a+b) higher than 32%, normal shape higher than 14%) according to WHO standards[1].

Which products are used for MHC, in what form and how often?

The most widely used treatment is testosterone enanthate (TE) in the form of oily, intramuscular injections with a dose of 200 mg once a week.

Treatment duration must not exceed 18 months.

On this subject, we can quote the WHO expertise (excerpt of a protocol that has been approved by the toxicology group and the advisory committee on human research):

“The 200 mg intramuscular dose of TE has been administered by different authors during various previous studies conducted on normal men. All of these studies have provided a great amount of data regarding sperm analyses, rates and serum hormone profiles and side effects. The following side effects seem to be well established: moderate tendency to put on weight (2 kg in average), slight increase in haematocrit (2%) and occasional acne or detectable gynecomastia. Such reactions have rarely lead participants to interrupt the experiment protocol. Nothing shows that this treatment could lead to prostatic hyperplasia and in any event, the men included in this study all belong to an age group (25–45 years old) in which there are no chances of prostatic failure. No report mentions acute toxicity and in particular signs of hepatic diseases when this scheme relying on TE is applied to normal men [2].

TE has been marketed worldwide for over 30 years. It has been used for therapeutic purposes often for dozens of years by thousands of men with hypogonadism, usually with a 250/220 mg dose every 10 to 14 days.

No author reported that this substance was toxic in these therapeutic schemes.”

At which point does a man using MHC has reached a contraceptive condition?

Once the concentration of spermatozoa is below 1 million/ml. This concentration level must be obtained between one and three months of treatment. If after three months the concentration of spermatozoa is higher than 1 million/ml, the treatment is stopped and we tell the candidate that they're not part of the good responders for ill-identified biological reasons as of yet.

Should they continue to have sperm analyses?

If the man takes his treatment appropriately, one sperm analysis per trimester is enough. This test reassures the couple and is used to make sure the treatment is correctly followed.

For how long can a man use MHC?

For 18 months according to wide-scale WHO protocols.

Is MHC reversible and within how long?

MHC is perfectly reversible. Depending on the person, getting back to the same sperm count as that preceding the treatment happens over varying timeframes. But fertility can be restored very quickly, as soon as one month after the treatment was stopped.

In our experience [3], one month after stopping the treatment 70% of the participants had a concentration of spermatozoa higher than 1 million/ml, and of those 70%, 20% had over 20 million spermatozoa/ml.

This has been quantified in an analysis conducted on 1,549 men. The average time needed to recover a 20 million/ml concentration was estimated at 3,4 months [4].

What are the side effects of MHC?

They have been well identified (see also the answer to question 3).

Under the aforementioned conditions, the effects are benign. More precisely, in a group of 157 men following the treatment [5], we decided to stop the treatment for 25 of them (16%) for the following reasons: acne ($n = 9$),

aggressivity, excessive libido ($n = 3$), weight gain ($n = 2$), lipid alteration ($n = 2$) or hematocrit alteration ($n = 2$), hypertension ($n = 1$), depression ($n = 1$), asthenia ($n = 1$), aphthous stomatitis ($n = 1$), acute prostatitis ($n = 1$), pneumonia ($n = 1$) and Gilbert's syndrome ($n = 1$).

Is an annual check-up necessary while on MHC?

A clinical assessment (designed to assess efficiency and side effects of the treatment) and a biological assessment carried out every 6 months seem advisable based on current evidence. The biological assessment is simple (FBC, ASAT, ALAT, GGT, blood lipids).

MTC in nine questions (R. Mieusset)

For which men does MTC seem acceptable?

All men living with a partner and accepting that their partner is orally informed of the method used, whatever the motivation behind it: the wish to balance contraceptive responsibility within the couple, preserving the health of the woman (adverse effects of or medical contraindication to female contraception methods), wish to control his fertility on the part of the man.

In our experiences on 17 couples who are using or have used MTC has a couple contraception method:

- in 6% of the cases, the woman had suffered from genital infections after an intrauterine device had been placed;
- in 18% of the cases, female hormonal contraception (pills, implant) had caused metrorrhagia or hyperlipidemia;
- in 24% of the cases, the woman wished to stop using the pill on the long run and to stop assuming the couple's contraception alone;
- in 18% of the cases, the couple used the condom and/or withdrawal or a vaginal ring and wished to switch to a male non-hormonal contraception method;
- in 34% of the cases, the man wanted to share the contraceptive responsibility without resorting to MHC.

Which clinical and biological assessments should be required from a man wishing to use MTC? What are the contraindications to MTC?

In the absence of previously conducted studies, MTC is not recommended to men whose

- oral examination reveals the following history:

- Testicular descent anomalies (cryptorchidism, ectopia), treated or not; inguinal hernia, treated or not;
- testicular cancer;
- clinical examination shows: grade 3 varicocele; severe obesity;

No blood test is required.

Lastly, the *seminogram* must be considered normal: concentration of spermatozoa higher than 15 million/ml, progressive motility greater than 32%, normal morphology depending on the method used

Which techniques are used for MTC, in what form and how often?

The most widely used method consists in raising the temperature in the testicles by about 2°C. This rise in temperature is obtained by moving the testicles from the scrotum to the superficial inguinal sac. The testicles are then held in this position using two techniques:

- surgical “suspension” of the testes [6]: this method requiring surgery does not seem acceptable to us and will not be described here;
- testicular “lifting” which we favour.

Principle: Each testicle is manually “lifted” from the scrotum to the root of the penis, close to the external orifice of the inguinal canal. The testicles must be held in this position every day during waking hours (15 hours a day).

Implementation and results Testicular lifting¹ is possible without any risks for all men meeting the defined inclusion criteria (see answer to question 2). We have made three consecutive improvements to the holding method which have resulted in a technique that can be shared and evaluated on a large scale.

First step ($n = 14$ men):

- the testicles are maintained with the help of snug underwear (95% cotton, 5% elastomer) in which a hole is created at the root of the penis. With a light manual pulling movement, the man can put his penis as well as the scrotal skin through this hole, which brings the testicles up in the desired position;
- after 6 to 12 months, the concentration of *mobile* spermatozoa is comprised between 1 and 3 million/ml [7].

Second step ($n = 6$ men):

¹ The author can forward a short slideshow on the practical execution of the movement.

- a flexible rubber ring was added around the hole in order to better hold the testicles in the desired area;
- the inhibiting effect of this process is significantly higher: within 3 months, the concentration of *mobile* spermatozoa is lower than or equal to 1 million/ml [8].

Third step and current method ($n = 5$ men):

- the rubber ring has been replaced by elastic fabric strips sewn directly on the underwear;
- this adjustment allowed us to reach the contraceptive threshold (less than 1 million *mobile* spermatozoa/ml) within the first three months of use [9].

The contraceptive efficiency of these methods was established by two studies:

- testicular “suspension”: 28 couples, 252 cycles of exposure to pregnancies: no pregnancies [6];
- testicular “lifting”: 9 couples, 159 cycles of exposure to pregnancies: one pregnancy, due to improper use of the method (the underwear was not worn for seven weeks). If we exclude the cycle that resulted in a pregnancy while keeping this couple who then started using the testicular lifting technique again as their sole couple contraception method, there were no pregnancies for 158 exposure cycles [10]. *The underwear must be worn every day for a minimum of 15 hours a day. Failure to respect this minimum period of time every day or staying one day without wearing the underwear do not guarantee the inhibiting effect on spermatogenesis any more, and thus the contraceptive effect.*

At which point does a man using MTC has reached a contraceptive condition?

Once the concentration of *mobile* spermatozoa is inferior to 1 million/ml in two consecutive sperm samples taken three weeks apart. This concentration is obtained within two to four months of treatment.

Do you need to continue doing semen analysis after that?

It is advised to take a monthly test up to the sixth month, then every two months after that if the man properly applies his treatment. This test is a way of controlling that the treatment is applied properly and that the desired effect endures.

For how long can a man stay contracepted with MTC?

The maximum period is four years since reversibility in terms of sperm parameters and fertility has been observed for this period of time

Is this MTC method reversible? Within how long?

Testicular suspension After they stopped using the suspension method, the values of the spermatic parameters went back to normal for all men within 6 to 9 months. All the couples who subsequently wished to get pregnant did and no anomalies were found. No spontaneous miscarriages occurred [6].

Testicular lifting After the man stops wearing the underwear, the concentration of *mobile* spermatozoa gets back to the initial values within six to nine months. All the couples who subsequently wished to get pregnant did and no anomalies were found. No spontaneous miscarriages occurred [10]. It should be mentioned that an undesired pregnancy occurred three months after the man stopped wearing the underwear in a couple that wasn't using any other contraception method; which goes to show that the fertilising power of the spermatozoa can be effective again before all spermatic parameters are completely back to normal. Consequently, once MTC is stopped, another contraception method is *immediately* required to avoid any pregnancies.

What are the side effects of MTC?

No side effects have been observed during the application of MTC whether it was with suspension techniques (aside from surgical suspension) or testicular lifting.

Is an annual health check required when applying MTC?

No annual health check is required when applying MTC.

Conflict of interests statement: The authors declare no conflict of interest

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