

The Estimation of Male Contraceptive Methods' Development Considering Legal, Ethical, and Religious Aspects

Anindya Hapsari

Department of Public Health, Sport
Science Faculty
Universitas Negeri Malang
Malang, East Java, Indonesia
anindya.hapsari.fik@um.ac.id

Sepfrita Katerine Aftabuddin

Wakai Public Health Center
Tojo Una-Una District, Central Sulawesi,
Indonesia
sepfrita_k@yahoo.com

Abstract— Contraceptives are tools that are used to prevent conception. The aim of these tools is to control population growth by controlling the rate of birth. There are many contraceptive methods, but male participation rate are still low. Until today, male contraceptive methods are still limited. And these methods had so many weakness, including: uncomforness, needed operation technique, or still controversial from religion aspect. Thus, there are still needed to conduct research to develop male contraceptive methods. These research have to consider all aspects: legal, ethics, and also religion, so that can be found male contraceptive methods that are easy to use, safe, efective, reversible, minimum side effects, and can be used by all people in community. This paper will provide the estimation of male contraceptive method' development considering legal, ethics, and religion aspects.

Keywords— male contraceptive method, legal aspect, ethic aspect, religion aspect

I. INTRODUCTION

Efforts to control population in Indonesia begin with the declaration of Family Planning (*Keluarga Berencana*; KB) program in 1970. The purpose of this KB program is to restore health and prosperity of mothers, children, family, and nation and to reduce birth rate in order to improve living standards of the population and nation [1]. The implementation of KB program requires the use of contraception as a measure in preventing fertilization. Contraception is a method used to inhibit or delay pregnancy [2]. Generally, contraception works by preventing the interaction of spermatozoa and mature oocyte, thus preventing conception.

There are various methods of contraception available to use by both men and women. These methods include natural method, operative procedure, and the use of instruments or contraceptive drugs. The choice of contraception can affect long-term sexual health and also fertility of both men and women [3].

Contraceptive methods for men are more limited and have slower development compared to contraceptive methods for women. This may be due to the complexity of fertility system of men where spermatozoa are always produced in a huge

amount throughout a man's life. Therefore, to regulate men's fertility, new and effective contraceptive method for men is a high priority for WHO Task Force [4].

Not all current contraceptive methods for men are acceptable by certain community. Particular religions have a strict rule regarding contraception and KB. The development of contraceptive method for men should consider all sorts of aspects. This article presented the history regarding the use of contraception for men, epidemiology, methods of male contraception, and viewpoints regarding men contraception from all aspects. Therefore, the developmental direction of future contraception for men can be expected.

II. RESULT OF REVIEW

A. The History of Male Contraception

Contraceptive method for men is actually the first method used to control population growth rate. However, with the finding and advancement of hormonal contraceptive method for women, the development of contraception for men became very slow [5].

Until the middle of the 20th century, men contraceptive methods such as calendar method (fertility awareness), withdrawal, condom, and vasectomy are the only contraceptive methods used. Introduction of hormonal contraception for women in the form of pills around 1950 and 1960 started new era of hormonal contraceptive methods and various other contraceptive methods for women [4].

The principle of hormonal contraceptive method for men and women is the repression of gonadotropin hormone level to prevent the occurrence of the process of folliculogenesis and steroidogenesis of ovarium and the process of spermatogenesis and steroidogenesis of the testis. However, the development of hormonal contraceptive methods for men is not as fast as those for women. One of the reasons was lack of knowledge regarding complex regulation mechanism of normal spermatogenesis process [6].

A study showed that testosterone level in the testes is higher than in circulation. However, functional significance from high testosterone level in testis is still not certain. A study also reported that Leydig cells still produces testosterone after hypophysectomy [4]. Hormonal regulation system and continuous spermatogenesis process become challenges in studies about contraceptive methods for men.

B. Epidemiology of Male Contraception

According to the data from Badan Kependudukan dan Keluarga Berencana Nasional (BKKBN) in 2011, the involvement of men as new contraceptive users showed 47,824 men who used condom (6.47%) and 2,508 men who underwent vasectomy (0.34%) [7]. Data regarding men using withdrawal or fertility awareness method are not known for certain.

Based on a study conducted by Weber and Dohle in 2003, it is estimated that as many as 45 million men performed vasectomy, 49 million men used condom, and 41 million men used withdrawal for their contraceptive methods. The study also showed that most men from various community have the willingness to share responsibility of contraception with their partners. However, not all men are willing to accept injection and transdermal method as hormonal contraceptive methods [4].

C. Methods of Male Contraception

Various contraceptive methods available for men and are currently tested and developed are as follows:

1) Condom

Condom is the oldest barrier contraceptive method available. Various forms of men condoms have been used as a method of contraception for centuries. Generally, men condom is in the shape of a sheath slipped through the penis before ejaculation. Condom is made from latex and has been mass produced since mid-1800. Condom has been available in generous amount since 1930 with the purpose of preventing pregnancy and sexually transmitted diseases. Until currently, condom has been one of the most popular and mostly used method of men contraception. Failure of condom in preventing pregnancy often caused by user's mistake and discontinued use. Condom is still one of the most effective method of contraception with failure rate of 2% in the first year of use [8]. Condom is also the most popular method of contraception to prevent the risk of sexually transmitted diseases caused by bacteria, viruses, or parasites [9].

2) Withdrawal

This contraceptive method has no side effects. However, the failure rate is quite high with pregnancy rate reaching 18 out of 100. The complaints of this method are discomfort and late of pulling the penis before ejaculation [4].

a) Calendar Methods/Fertility Awareness

This method is used by not performing coitus during woman's fertile period. This method is quite effective to

prevent pregnancy as long as fertile period is precisely known. Failure rate of fertility awareness method in the first year is 20% [4].

b) Vasectomy

Vasectomy is a procedure of cutting, binding, or sealing right and left vas deferens in order to prevent spermatozoa from coming out with ejaculates during ejaculation. This method requires minor surgery with short duration. Vasectomy is a highly effective men contraceptive method. The failure rate is less than 1%. Early complications that may occur after the procedure include: hematoma, infection, sperm granuloma, and congestive epididymitis. These complications only occur in 1-6% of men undergoing vasectomy. Epidemiological studies fail to show any relationship between vasectomy and cardiovascular diseases. Various results data from other studies also showed no indication that men who underwent vasectomy have the risk of prostate and testicular cancer [4].

c) Male Hormonal Contraception Method

Men hormonal contraception is a method of contraception based on the suppression of gonadotropin and substitution of testosterone. Testosterone is needed to maintain sexual function in men, bone mineralization, and muscle strength. Effective hormonal contraception should be able to inhibit total spermatogenesis process and adequately suppress the production of intratesticular testosterone [4].

Because testosterone and FSH are both needed for normal spermatogenesis, then the most realistic way to inhibit spermatogenesis is by suppressing endocrine stimulation by hypophyseal gonadotropin. Suppression of gonadotropin is expected to reduce intratesticular testosterone and suppress the function of FSH, thus preventing maturation of spermatogonia and disrupt spermatogenesis in premeiotic stage without affecting primordial cells [4].

A study regarding hormonal contraception for men has begun since around 1970s. Results showed that the use of exogenous testosterone is highly effective in suppressing the production of testosterone and spermatogenesis with minimum side effects. The addition of progestin preparations in hormonal contraceptive formulation will increase suppression level of spermatogenesis. Possible side effects include acne, pain in injection site, mood swings (including depression), and mild temporary libido changes [10].

Various hormonal contraceptive preparations have been developed and tested with various clinical tests. These preparations include: testosterone, combination of androgen/progestin, testosterone with GnRH analogue, and receptor selective modulator for androgen and progestin. Combination of testosterone and progestogen, until now, has been the preparation with the most promising result as hormonal contraceptive method for men. The main drawback of this method is only a few of androgen formulation results that were satisfactory. Other than that, during clinical tests, imperfect suppression of spermatogenesis was found in and between population group. The results of this clinical test also

showed that Asian men that were given testosterone/progestogen preparations exhibited higher spermatogenesis suppression compared to European or American. Spermatogenesis suppression is characterized by high azoospermia count. Other study in Asian men also showed high azoospermia count when given only testosterone preparation and combination of androgen/progestogen [4].

Hormonal contraception for men by means of administration of exogenous testosterone and progestin will suppress LH and FSH, and intratesticular androgen levels to the lowest level. The exact level is needed to enable reversibility of reproductive function after discontinuation of contraceptive use. Men hormonal contraception needs quite long onset, i.e. around 6-8 weeks. Fertility return after discontinuation of use is also around 6-8 weeks [11].

Besides testosterone, progestin, and androgen, other hormone preparations that were also proven to reduce FSH level *in vivo* (in male rats) was inhibin B. Inhibin B is the hormone produced by Sertoli cells of the testes and acts to suppress the release of hypophyseal FSH. A study by Akmal in 2015 was capable to isolate inhibin B from the testes of male rats and proved that exogenous inhibin B injection can suppress FSH level, thus suppressing spermatogenesis. Further study is still conducted to determine the reversibility and toxic dose of inhibin B [12].

The administration of men hormonal contraception is not as easy as oral contraceptive administration in women. Men hormonal contraception containing testosterone cannot be packed in oral pills. This was due to testosterone consumed orally is immediately inactivated by first-pass effect of the liver. Therefore, hormonal contraceptive administration should be done parenterally by using implant or injection [13].

Current studies are focused in developing men hormonal contraception in the form of long-acting injection and transdermal gel [10]. Preparations available currently are testosterone and gestagens injections. The injections were given every 2-3 months, similar to progestin in women [13].

The disadvantage of hormonal contraceptive method for men is that they give no protection to sexually transmitted diseases. Therefore, the target population for this type of contraception are men with low risk of sexually transmitted diseases. The advantage of this hormonal contraceptive method is the reversibility or the return of fertility after discontinuation of contraceptive use. Meanwhile, several short-term studies (until 30 months) proved the safety of this method by showing no hazardous side effects. Other advantages are increased muscle mass and strength, reduced fat mass, and protection to metabolic syndrome and the risk of cardiovascular disease [11].

d) Male Nonhormonal Contraception Methods

Experiments had been done in order to discover new male contraception methods by finding nonhormonal substances that can disrupt spermatogenesis, or inhibit spermatozoa's functions. These nonhormonal methods have potencies to

affect male fertility without involving hypothalamus-pituitary-testis axis. Some of male nonhormonal contraceptive methods that had been explored and developed are:

Gossypol can effectively suppress spermatogenesis, but its effect is not always reversible. Beside that, gossypol had been reported for its effects on lowering blood potassium and blocking calcium channel [4].

Calcium channel blockers (CCB) are commonly used as therapy for angina, arrhythmia, or hypertension. Lately, these CCB are found to have contraception effect by changing the shape, activation, acrosome reaction, and the function of spermatozoa [5].

N-butyldeoxynojirimycin (NB-DNJ) that are given orally to mice could inhibit *ceramide-specific glucosyltransferase* which are enzymes needed to synthesize ganglioside. Ganglioside is an important protein for spermatogenesis [5]. The other research by Weber and Dohle also showed that NB-DNJ that are given orally could suppress fertility on mice [4].

e) Anti-sperm Contraceptive Vaccine

Researches about vaccine for contraception targeting sperm are based on mechanism to block spermatozoa maturation in epididymis using vaccine to spermatozoa's specific protein [4]. Research conducted by Santhanam and Naz (2001) could isolate specific protein on human spermatozoa. The success of isolating these proteins triggered other researches to continue this research to make specific vaccines targeting human sperm [14].

In the other hand, other research had been successful to isolate eppin (*epididymal protease inhibitor*) which is specific protein expressed on testis and epididymis. Eppin bonded to spermatozoa and played role in activating maturation process of spermatozoa. Thus, research on animal model is conducted to know the potency of eppin as vaccine for contraception [5].

D. Aspects of Male Contraceptive Methods

1) Legal Aspect of Male Contraceptive Methods

In Indonesia, contraceptive services are contained on Undang-Undang Nomor 52 Tahun 2009 about The Development of Population and Development of Family. On that constitution, there are chapters that conduct about the implementation of family planning program and contraceptive services considering ethics and husband-wife reproductive rights [15]. Meanwhile, contraceptive methods that are legal to use in Indonesia are contained on Peraturan Menteri Kesehatan Republik Indonesia Nomor 97 Tahun 2014 about Health Services Before Pregnant, On Pregnant, and After Birth; The Contraceptive Services; and Sexual Health Services [16].

Based on chapter 22 and 23 Permenkes No 97 Tahun 2014, male contraceptive methods that are legal to use in Indonesia are condoms and Male Operation Methods (vasectomy) [16]. Natural methods such as calendar methods and withdrawal are not contained on the constitutions. Likewise, male hormonal contraceptive methods, male nonhormonal contraceptive

methods, and anti-sperm vaccine haven't been included on legal constitutions in Indonesia. This is because these contraceptive methods haven't been available and human clinical trial are still on progress.

2) *Ethics Aspect of Male Contraceptive Methods*

Considering ethics aspect, there are many sights about the using of male contraception. As contained on Undang-Undang Nomor 52 Tahun 2009 about The Development of Population and Development of Family, the choosing of contraceptive methods have to through the agreement of both husband and wife so it is said relevant to ethics [15]. But, there is also an ethical sight that assume that the using of contraception violated human right due to disturb normal function of the body. There is also another assumption that said that the responsibility to role birth are on women, so male contraception aren't needed [4]. In Indonesia, according to Undang-Undang Nomor 52 Tahun 2009, male contraceptive methods that are available in Indonesia are appropriate ethically, as long as the using are through the agreement of both husband and wife [15].

3) *Religion Aspects of Male Contraceptive Methods*

In general, all religions allow people to use contraception. But, some religions have their own sights to family planning, including contraception as tools to regulate birth.

a) *Islam*

Indonesian Ulema Council as Indonesia's top muslim clerical body that provide halal-certification for Muslim community, has produced fatwa about the permission of Muslim community to use contraception. Indonesian Ulema Council's fatwa about family planning was established on National Ulema Mukhtar about Population, Health, and Development that was held in Jakarta on October 1983. Vasectomy as one of male contraceptive method had been provided as fatwa 4 times. In 1979, 1983, and 2009, vasectomy was produced as haram-fatwa because this method was assumed to cause permanent sterility. In 2012, Indonesian Ulema Council was revised the haram-fatwa to become haram-except [17]: (1) the purpose isn't against syari'at; (2) doesn't make permanent sterility; (3) there is a guarantee that recanalization can be done, so that reproduction function will be recovered; (4) there is no harmful effect (madarat) for the user; (5) this method isn't included in program and method of permanent contraception.

b) *Christian and Catholics*

Christian and Catholics allow their community to use contraception as a part of family planning, with some restrictions. Contraceptive methods that aren't allowed are abortion, withdrawal, and sterilization. Church suggests their community to use calendar method. If this method is difficult to do, the husband-wife can ask advice from father as imam to find a better and suitable method of contraception [18].

c) *Hinduism*

Hinduism supports all family planning's programmes and the using of contraception because the Hindus finds that these programmes are parallel with the dogma of the religion. Based on Hindu religion, the contraceptive methods that are found from elaborating science and used for people welfare, would be accepted by Hindu Dharma. Hindu religion also regulates the using of contraceptive methods based on place, time, and situation [18].

d) *Buddha*

Buddha religion isn't opposed to the using of contraception in order to regulate the number of population. The buddhist are allowed to use contraception because contraception means to prevent pregnancies that are similar with prevention of spermatozoa and ovum to be met. The buddhist believe that spermatozoa and ovum aren't life being, so that preventing these two to meet isn't same with a murder to life [18].

Based on the explanation of the religions in Indonesia, until today, male contraceptive methods that are allowed by all religions are calendar method and condoms. Vasectomy and withdrawal are not allowed by Catholics. Whereas, hormonal, nonhormonal, and anti-sperm vaccine haven't been concluded yet because these methods are still unavailable in Indonesia.

III. THE ESTIMATION OF MALE CONTRACEPTIVE METHODS' DEVELOPMENT CONSIDERING LEGAL, ETHICS, AND RELIGION ASPECTS

Considering legal, ethics, and religion aspects, male contraceptive methods' that will be developed are hormonal and nonhormonal contraception. The reasons of this estimation are because these methods of contraception have good effectivity and probably can be accepted by all people in community. These contraception methods aren't sterilization method and can guarantee reversability after stopping to use these contraception.

The next nonhormonal researches probably will focus on the invention of new substances which have function as contraception or antifertility. These substances may be found on plant's extract, such as gossypol on cotton oil. In the other hand, the researches of hormonal contraception will still search suitable application method and precise hormonal formulation so these can prevent spermatogenesis and steroidogenesis perfectly.

The other method that can be developed is anti-sperm vaccine. Researches that conduct to isolate specific protein from testis, epididymis, or spermatozoa will still be done as an effort to develop high-specificity-vaccine. Compared to hormonal and nonhormonal methods, the development of anti-sperm vaccine will probably be less. Maybe this is because there is anti-vaccine community in Indonesia so that the using of vaccine as contraception won't be accepted.

Male condom can also be developed. As an effective, legal, and permitted method of contraception, male condom has a good prospect to be more elaborated. Researches will conduct to find more proper materials to make condoms so the next male condom will be less irritating, thinner, and achievable.

IV. CONCLUSION

The using of contraception is an effort to control population by controlling birth. There are many contraceptive methods that are available and can be used for male or female. The development of male contraceptive methods are slower than female and male participation rate are still low. The reason may be because there are some male contraceptive methods that can't be accepted by some people in community. Considering all aspects, we've reached decision that male contraceptive methods' that will be developed more are hormonal and nonhormonal contraception. The reasons of this estimation are because these methods of contraception have good effectivity, acceptability, and reversability compared to other contraception methods, considering legal, ethics, or religion aspects.

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