Al-hajah Tunazzal Manzilah Al-darurah in prevention Venous Thromoembolism (VTE) during pregnancy and puerperium

Al-Hajah Tunazzal Manzilah Al-darurah en prevención Tromoembolismo venoso (TEV) durante el embarazo y el puerperio

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ABSTRACT

Fatwa on Clexane and Fraxiparine which are used for Venous Thromboembolism (VTE) during pregnancy and puerperium, imposed by the Malaysian National Fatwa Council (MNFC) in 2009 stating that both types of low molecular weight heparin (LMWH) is prohibited except in darurah only due to its porcine preparation ground. Thus, this paper embarks to expound to which extent unlawful sources for medical prevention and treatment can be used for Muslim consumption. Is it only when a darurah condition is announced as an exemption situation that the intoxicating material is allowed in medicine? This research employs qualitative methodology using document review method to analyse the content of the document including medical journals and Shariah books. Observing the alarming maternal mortality due to VTE during pregnancy and puerperium in Malaysia nowadays, it is true that VTE is a fatal and life threatening illness. Due to that, LMWH is recommended by the Ministry Health of Malaysia (MOH). With LMWH features of accessibility, feasibility, effective and safety profile, it becomes the first line of option among O&G doctors in Malaysia albeit it is porcine based. Therefore, this paper found that the prevention of VTE using LMWH when diagnosed as a moderate risk during pregnancy and low risk during puerperium is allowed in the shariah perspective based on Islamic legal maxim namely Al-Hajah Tunazzal Manzilah Darurah.

Keywords: Low Molecular Weight Heparin (LMWH), Venous thromboembolism (VTE), Darurah, Al-hajah tunazzal manzilah darurah.

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RESUMEN

Fatwa en Clexane y Fraxiparine, que se usan para el tromboembolismo venoso (TEV) durante el embarazo y el Fatwa sobre el clexano y la fraxiparina que se utilizan para la tromboembolia venosa (TEV) durante el embarazo y el puerperio, impuesto por el Consejo Nacional de Fatwa de Malasia (MNFC) en 2009, en el que se establece que ambos tipos de heparina de bajo peso molecular (HBPM) están prohibidos, excepto en el darurah, debido únicamente a su preparación porcina molida. Así pues, el presente documento se propone exponer en qué medida las fuentes ilegales de prevención y tratamiento médicos pueden utilizarse para el consumo de los musulmanes. ¿Sólo cuando se anuncia una condición de darurah como situación de exención se permite el material intoxicante en la medicina? Esta investigación emplea una metodología cualitativa que utiliza el método de revisión de documentos para analizar el contenido del documento, incluidas las revistas médicas y los libros de la Sharia. Observando la alarmante mortalidad materna debida a la ETV durante el embarazo y el puerperio en Malasia hoy en día, es cierto que la ETV es una enfermedad mortal y que amenaza la vida. Debido a ello, la HMG es recomendada por el Ministerio de Salud de Malasia (MOH). Con las características de accesibilidad, viabilidad, efectividad y perfil de seguridad de la HBPM, se convierte en la primera línea de opción entre los doctores de O&G en Malasia, aunque sea de origen porcino. Por lo tanto, en este documento se constató que la prevención del TEV mediante HBPM cuando se diagnostica un riesgo moderado durante el embarazo y un riesgo bajo durante el puerperio está permitida en la perspectiva de la sharia basada en la máxima legal islámica, a saber, Al-Hajah Tunazzal Manzilah Darurah.

Palabras clave: heparina de bajo peso molecular (HBPM), tromboembolismo venoso (TEV), Darurah, Al-hajah tunazzal manzilah darurah.

RESUMO

Fatwa em Clexane e Fraxiparine, usados para tromboembolismo venoso (TEV) durante a gravidez e o puerpério, impostos pelo Conselho Nacional da Fatwa da Malásia (MNFC) em 2009, afirmando que os dois tipos de heparina de baixo peso molecular (HBPM) são proibidos, exceto em Darurah apenas devido ao seu terreno de preparação de suínos. Assim, este artigo embarca para expor em que medida fontes ilegais de prevenção e tratamento médico podem ser usadas para o consumo muçulmano. Somente quando uma condição de darurah é anunciada como uma situação de isenção é que o material intoxicante é permitido na medicina? Esta pesquisa emprega metodologia qualitativa usando o método de revisão de documentos para analisar o conteúdo do documento, incluindo revistas médicas e livros da Shariah. Observando a alarmante mortalidade materna devido ao TEV durante a gravidez e o puerpério na Malásia atualmente, é verdade que o TEV é uma doença fatal e com risco de vida. Por esse motivo, a HBPM é recomendada pelo Ministério da Saúde da Malásia (MS). Com os recursos de acessibilidade, viabilidade, perfil efetivo e de segurança da HBPM, ela se torna a primeira linha de opção entre os médicos de O&G na Malásia, embora seja baseada em suínos. Portanto, este artigo descobriu que a prevenção de TEV usando HBPM quando diagnosticada como risco moderado durante a gravidez e baixo risco durante o puerpério é permitida na perspectiva da sharia, com base na máxima legal islâmica, a saber, Al-Hajah Tunazzal Manzilah Darurah.

Palavras-chave: Heparina de baixo peso molecular (HBPM), tromboembolismo venoso (TEV), Darurah, al-hajah tunazzal manzilah darurah.

1. Introduction

Recent statistics of Malaysia data in 2016 dragged citizen's attention when a report indicates that death due to obstetric embolism highest percentage for maternal deaths 23.0%. Other maternal complications cause of death in Malaysia in 2017 are ranked according to their percentage as recorded in press release statistics on causes of death, Malaysia, 2017 deaths as follows: childbirth and puerperium (18.2%), postpartum hemorrhage (11.5%), ectopic pregnancy (6.8%) and eclampsia (6.1%). (Department of Statistic, 2017).

Even though the world witnesses the significant decline from 44 per 100,000 LB in 1991 to 23 per 100,000 LB, (Department of Statistic, 2017) of maternal mortality in Malaysia from 1991 to 2015 (Yadav, 2014, A'isyah, 2018, Ravichandran & Ravindran, 2014, Hematram, 2006, Achanna et al., 2018) but Malaysia still needs to intensify the safer motherhood because thromboembolism is still the leading cause of maternal mortality (MOH, 2013) as stated in 2016 statistics report displays the major cause of maternal mortality is obstetric embolism.

Venous Thromboembolism (VTE) includes two popular kinds: Pulmonary embolism (PE) and deep vein thrombosis (DVT) (Bates et al., 2016). Confidential Enquiry Maternal Death (CEMD) of Malaysia reported around 2009 - 2014, there were 68 deaths caused by obstetric VTE in the period from 2012 to 2014, with 41 deaths (60.3%) due to blood clot embolism and 27 deaths (39.7%) due to amniotic fluid embolism (MOH, 2018).

Based on data published in 2010, women delivered by caesarean section in Malaysia have been gradually increasing. (Karalasingam et al., 2012) Operative delivery has higher risk (Walsh & Malone, 2016) to be indicated as VTE carrier

without excluding other lifestyle factors such as obesity, age above 35 years, smoking and immobility (MOH, 2014). Embolism is considered as significant cause of maternal mortality in Malaysia.

Regarding that reality, LMWH such as Clexane is recommended as anticoagulant to prevent VTE before it is formed during pregnancy and puerperium. However, JAKIM (2015) had issued a fatwa of Enoxaparin Sodium (Clexane) and Fraxiparine be gazetted by MNFC on 23rd-25th June 2009. It is stated that Enoxaparin Sodium (Clexane) and Fraxiparine is prohibited with exceptional for patients with *darurah* level.

It is undeniable that Islamic medical jurisprudence revealed ruling to cure dangerous disorders with prohibited (*haram*) substances in *darurah* in Islamic situations (Azri et al., 2017) but there should be a room for some enquiries regarding the *fiqhu al-waqi* and *fiqhu al-aulawiyat* which present to us the need to consider on relevant physiological in pregnancy.

Indeed, prevention is better than cure and VTE must be prevented from pregnant and puerperium women due to wellbeing (*maslahah*) of human lives. Therefore, this research is intended to answer the following research question:

Based on the current maternal mortality related VTE during pregnancy and puerperium, do the argument of *hajah tunazzal manzilah al-darurah* is irrilevant to the prescribed LMWH upon moderate risk during pregnancy and low risk with complication during puerperium?

Al-Hajah is a concept that is integrated closely to the concept of darurah in Islamic fiqh discipline. There is a distinguished criterion of hajah which differs from darurah despite the literal definition darurah directly quoted al-hajah ila al-syaik. This topic will explain about the concept of al-hajah al-syar'iyyah in terms of definition, the dawabit of al-hajah and the qawaed fiqhiyyah which relate to al-hajah al-syar'iyyah, how hajah concept is able to be as crucial as darurah situation and the implication of hajah in its implication to Islamic legal rule for thromboprophylaxis with LMWH (Enoxaparin) during pregnancy and puerperium. Al-hajah is a noun, called in Arabic isim masdar from the word hawaja (PPP) defined as al-idtirar ila al-syaik (Ibnu Faris, 1979). Al-Fairuz Abadi stated that the word al-hajah denoted to al-darurah. Ibnu Subki (n.d.) clarified literally darurah does not have any difference from al-hajah as quoted "ma yahtaju ilaihi mutlaqan wasalat al-hajah ila had al-darurah am la". Ibnu Manzur (1883) elaborated hajah as al-maarabah or al-rughbah.

Hajah is a need for something (*al-iftiqar ila al-syaik*). It is said, a man's need for money or a man's need for medicine. Thus, it is said that one who called in Arabic *al-faqir* is synonym to *al-muhtaj* (the one who need) for something either for shelter, food, drink or medicine (Al-Azhari, 1964).

Jurist opined that to ascertain the technical term for *hajah*, they lay the term in accordance to *maqasid al-shariah* context of understanding. On top of that, the term is based on two scholarly arguments is as follows:

First: The different arguments amongst Shariah scholars regarding *al-masalih* in Islamic rulings generally. *Al-Masalih* is essentially divided into three categories: *maslahah al-mu'tabarah*, *masalah al-mulghah* and *maslahah al-mursalah* (Al-Ghazali, 2008, Ibnu Qudamah, 1998, Ibnu Juzai, 2002). Hence, the term *hajah* technically denoted to the third category namely *maslahah al-mursalah* according to the jurists (Al-Rashid, 2008). *Masalih al-mursalah* is the contemporary issue which there is no dalil urged on it and no dalil found to object it.

Second: The second argument relies on the qiyas discussion with regard to *masalik al-'illah*. The argument is about *maslak al-munasabah*. The concept of *maslak* is divided into four types: *mu'sar*, *mula'im*, *gharib* and *mursal*. While *hajah* is discussed under the topic of *maslak al-ta'lil* (Al-Amidi, 2003).

Majority of shariah scholars defined *hajah* in general understanding with association to the concept of *darurah*. Islamic Fiqh scholars and jurists definitions are distinguishing *hajah* with a need for something without reaching out the level of *darurah* (Al-Juwayni, 1979).

1.1 Definitions of hajah according to contemporary scholars

Some contemporary scholars such as Syeikh Ahmad Zarqa' said, "Al-hajah is a condition when facility towards it is needed in order to achieve the objective without bother the level of darurah, the Islamic ruling with regard hajah is continuously exercised while the ruling of darurah is practiced for allocated time only" (1989). While, Dr Ahmad Abdul Rahman Nasir Al-Rashid indicated "need for something due to widening the tight and masyaqqah which is contradicted to the arguments (adillah) and qawa'ed al-syar'iah" (2008).

1.2 Hajah in medical perspective

The researcher infers that the *hajah* context in medical perspective differ from other fields, which is *hajah* is capable to approve or allow intoxicating ingredients in medicines as a way of prevention and treatment the diseases. Food area differs from pharmaceutical area by which in the medical perspective, Imam Bukhari was well aware about three components implied to medicine, they are for the 1) promotion of health 2) prevention of health 3) restoration of health (Deuraseh, 2006).

Indeed, prevention of any diseases using forbidden materials is classified as a tenacious need for that preventive medicine is permissible in Islam as the objective of shariah is to preserve human lives with practicing any of the three components stated. Furthermore, in the cases of being able to detect the symptoms, the sufferers are categorized as the desperate need for the medicine to curb it so as to prevent it. At that risk situation, *hajah* plays a pivotal role and has substantial impact in *ijtihad* and *fatwa*.

There are many *qawaed fiqhiyyah* which are related to *hajah* conditions which are capable to affect the *ijtihad* and *fatwa* and the most known *qaedah fiqhiyyah* for that *hajah* is, *Al-Hajah Tunazzal Manzilah Al-Darurah*. In the case of women with high risk and moderate risk for VTE disease, they are prioritized according to their assessment result to be prescribed the most effective and safest medicine by evidence such as LMWH (Enoxaparin). Rather, the prevention treatment (Deuraseh, 2006) before being diagnosed as VTE sufferer during pregnancy and puerperium or called as precautionary measurement (Al-Jauziyyah, 2003) for them to be given LMWH as recommended by MOH as the health professional body in Malaysia supposedly to be followed as *al-hajah tunazzal manzilah al-darurah*.

1.3 The limitation of hajah from shariah view

In recent decade, Islamic fiqh scholars have comprehensively discussed the matter of *hajah*. In contrast, scholars in the past did not focus intensely on *hajah* measurement and its limitation because the definition between both terms, *darurah* and *hajah* are distinguishable by many in their times and places (Kafi, 2004; Al-Rashid, 2008). However, the problem is getting complex recently as novel issues are geared towards halal and haram law to determine the Islamic legal rule for prevention treatment in medical cases.

In Islam, it is clearly stated that Muslims are allowed to have concession (*rukhsah*) when their lives will be terminated unless the porcine base medicine is consumed that is considered *darurah* situation. However, VTE patients during pregnancy and puerperium will be stratified into three groups of risk namely high risk, moderate risk and low risk. All of three groups are not diagnosed VTE yet, but the assessment is performed by clinicians to observe their percentage of risk of getting VTE disease.

Indeed, the risk assessment sheet is helpful for clinicians to observe which group of risk the women are at; high risk or moderate risk or low risk. Based on the CPG (MOH, 2018), high risk level is assessed as cumulatively 4 points and above. Moderate risk patients are evaluated as having a score of 3 while low risk patients scored 1 or 2 points in pregnancy. Meanwhile, during the puerperium term, the recommendation for thromboprophylaxis of LMWH (Enoxparin) begin at score 2 if associated with complication especially caeserean.

1.4 Arrangement of knowledge of occurrence (Maratib al-Idrak)

The risk assessment of VTE during pregnancy and puerperium is based on the score provided by MOH as the professional body consisting of medical experts. Even though *darurah* and *hajah* are not measured by percentage or numerical assessment, however, Islamic Fiqh scholars have discussed the percentage of the knowledge or experience to which extent things may occur such as Al-Shanqiti (n.d.) explained the differences of certainty (*yaqin*), conjecture (*ghalabah al-zan*), doubt (*syak*) and fancy (*wahm*) have their own percentage of possibilities of occurrence. Al-Shanqiti suggested the percentage as below.

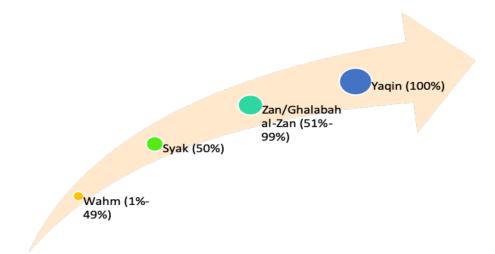


Figure 1. The percentage of possibilities of occurence

Yaqin equivalent to 100% is the highest verification that VTE will occur during pregnancy or puerperium because LMWH is a kind of preventive medicine which is stressed by some medical experts interviewed for this research that LMWH is assumed to reduce the maternal death by prevention dose to the women who are at risk. Further, zan or ghalabah al-zan or sometime called rajah is around 51% until 99% means the level of confidence measured as normally something may almost happen have based on knowledge and experience before. While, syak is accounted for 50% with example one had promised with her/his friend for outing. Then, that person knew that his/her friend is in the house but there is a feeling of likelihood in that the friend might go out. In turn, that feeling of possibility is called syak according to Al-Shanqiti. Finally, fancy or wahm approximately accounted for 1% until 49%, which means rare to happen or in Arabic called nadir.

Generally, legal proofs in shariah provides an exception to those who almost lost their lives at a level of certainty and conjecture to consume unclean and impure substances which we understand that exception is equivalent to having a high risk with a score of 4 and above, and moderate risk with a score of 3 during pregnancy on the basis of *darurah* and low risk with score 2 normally due to caesarean section on *hajah tunazzal manzilah al-darurah* argumentation, all of them to be prescribed LMWH as prevention.

2. Methodology

This research employs qualitative methodology with textual content analysis including medical documents and shariah books.

3. Results and discussion

According to the fatwa in 2009, it mentioned that LMWH such as Clexane and Fraxiparine is prohibited due to its source but it is allowed when it reaches the state of *darurah*. The state of *darurah* is clearly understood in the previous discussion. High risk group of mothers during pregnancy and puerperium are embedded in *darurah* principle. Nonetheless, how about the moderate risk group of mothers having been diagnosed with symptoms of VTE disease, instead their risk is positioned as moderate.

The principle of *hajah* in this research purposely meant it as *al-hajah tunazzal manzilah al-darurah*. In other words, the meaning of *hajah* in this moderate risk case is also judged as *darurah*. In fact, the *qaedah fiqhiyyah*, *al-hajah tunazzal manzilah al-darurah* is a branch of *qaedah kubra*, *al-masyaqqah tajlibu al-taysir* (Abdul Salam, n.d.). The relationship between both *qaedah* clearly shows to us that moderate risk group women who are at risk of VTE is actually treated as *darurah* condition.

Nonetheless, aligning with the stratifications of high-risk (score 4 and above) and moderate risk (score 3) during pregnancy and low risk (score 2) during pueperium is considered in a requirement for thromboprophylaxis with LMWH applied in CPG and training manual produced by MOH indicates that high risk patients with a score of over 3 is prooritized. Hence, the evaluation from shariah perspective that can be forwarded here is based on that CPG and training manual of VTE management.

Moderate term in a layman comprehension means less extreme, intense or violent. While, online dictionary

Cambridge states that moderate means neither small nor large in size, amount, degree, or strength, for example: a moderate intake of caffeine should not harm you (Dictionary Cambridge, n.d.). From that literal meaning, layman uses it as something that would not harm living things.

From the data obtained, most of them agreed that moderate risk or intermediate risk should be prescribed even though the condition is stratified as moderate risk term. In parallel, moderate risk factor of VTE is less violent than high risk factor but still in the scope of necessity which shall never be underestimated the crucial state of moderate risk to perceive thromboprophylaxis. This is based on the urge of prevention is better than cure as well as dependent on a *qaedah fiqhiyyah* called blocking the evil is prioritized than perceiving the benefit or in Arabic phrase, "dar'u al-mafsadah aula min jalbi al-maslahah" (Al-Suyuthī, 1983).

That *qaedah fiqhiyyah* directly answered to this issue in this research which categorizes a preventive treatment upon pregnant and puerperium women with unlawful sources of medicine specifically porcine, is actually allowed and permitted in the sight of shariah. Moreover, the symptoms or risk factors related to VTE during pregnancy and puerperium are the firm reason for mothers to receive thromboprophyklaxis with LMWH. This is supported with an elaboration regarding *qaedah al-fiqhiyyah "dar'u al-mafsadah aula min jalbi al-maslahah*" which entails from *qaedah kulliyyah "la darara wa la dirar"* clarifies that if the *mafsadah* is more dominant than *maslahah*, then blocking the *mafsadah* occurrence is eligible to be prioritized than attaining the *maslahah* (Al-Suyuthī, 1983; Ibnu Nujaym, 1999; Ali Haidar, 2004). Further, this *qaedah fiqhiyyah* is relevantly applicable to the case of prevention of VTE during pregnancy and puerperium with LMWH either for high risk group or moderate risk group as suggested by *ahl al-khibrah* in the literatures and interview data.

1.1 Moderate risk with Score 3 during pregnancy and low risk with score 2 during puerpeirum shall offer for thromboprophylaxis with LMWH

Terminology of moderate or intermediate is used in VTE related obstetric case for those who are at risk for having VTE disease during pregnancy and puerperium to differentiate from high risk group which has confirmed greater harm than moderate risk. However, based on the data obtained from interview sessions with medical participants, moderate risk group mothers are also considered to be in *darurah* to receive thromboprophylaxis due to the risk factors as extracted few risk factors from Prevention and Treatment of Thromboembolism in Pregnancy and Puerperium: A training Manual (MOH, 2018).

Table 1. Examples of few risk factors associated with the score point of each risk extracted from the training manual produced by MOH in 2018.

Types of Risk	Specific Risk	Score Risk
Pre-existing	Medical comorbidities. (e.g Cardiac failure, active SLE, active tuberculosis, nephrotic syndrome, diabetic nephropathy, malignancies)	3
	Obesity: BMI ≥40 kg/m²	2
	BMI 30-39 kg/m ²	1
Obstetric Risk	Caesarean section (elective and emergency)	2
	Pre-eclampsia	1

A presentation of an extraction of some of the risk factors score taken from risk assessment of VTE as published by MOH is shown in Table 1. Moderate risk is equivalent to 3 point of scoring which obtained from the assessment by clinicians. In fact, each of the disease of medical comorbidities such as cancer, cardiac failure and the sort scores 3 points. The reality of the moderate risk is eligible to *darurah* ruling since medical experts suggest those who score 3 points are considered for thromboprophylaxis. This is based on the situation that can be stratified as *al-hajah al-masah* (Al-Asyqar, 2001).

The researcher observes from above diagram x, pregnancy itself is at the risk of getting VTE due to its normal physiological state (MOH, 2013), then women's condition with all the risk factors either pre-existing types or obstetric risk will burden and harm them greater. Hence, moderate risk group of mothers shall be prescribed with LMWH for prevention as the qaedah fiqhiyyah dar'u al-mafsadah muqaddam 'ala jalbi al-maslahah, Iza Ta'aradat mafsadatani, ru'iya a'zamuhuma bir tikabi akhafihima and irtikab akhaffu al-dararain is exactly arguing the moderate risk group with 3 points score as al-hajah tunazzal manzilah al-darurah.

That *qaedah fiqhiyyah* is relevantly justified to the moderate risk group of VTE to receive thromboprophylaxis as prevention medicine due to other significant risk factors such as thrombophilia, lupus, heart disease, sickle cell disease, fluid and electrolyte imbalance, postpartum infection, transfusion, women aged 35 and older (James et al., 2006) scored as 3 or moderate risk.

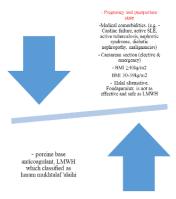


Figure 2. The weighing between two conditions; *mafsadah* and *maslahah* of VTE symtomatic women during pregnancy and puerperium.

4. Conclusion

Evaluating that condition which is more harmful than the following incidents which were narrated in hadith about treating with camel urine as a remedy for illness, preventing mangy skin by wearing silk garments and using fake nose made out of gold.

While, these pregnant women are known with current evidences are already at increased risk to develop VTE which can be fatal. Thus, it is very crucial to prioritize these women with VTE score of 3 and above to use the porcine based LMWH anticoagulant as prophylactic treatment (*min bab al-aula*).

Once the women are assessed as score 2 even though they are categorized as low risk, there are three different situations. First, if the women gave birth vaginally and do not have any complications with no VTE symptoms, then no prophylaxis with LMWH prescribed as there is no any legal cause to give LMWH based on *qaedah usuliyyah* "need is a cause of concession" or in Arabic, *al-hajah sabab al-rukhsah*.

According to the training manual by MOH, prophylaxis with LMWH is given to those who scored 2 points with complications. Therefore, they will be given LMWH as prevention of VTE after delivery. As long as the reason of scoring is still there, then LMWH is permissible to be consumed by Muslim women in that period based on qaedah fiqhiyyah dar'u al-maslahah muqaddam 'ala jalbi al-maslahah.

In conclusion, the researcher analyzed that women who are stratified at score 3 or moderate risk during pregnancy and score 2 during puerperium especially if caesarean is the delivery method then those women are regarded as *hajah tunazzal manzilah al-darurah*. This stance is supported by Hammad (2004) that Islamic Fiqh scholars such as Abu Hanifah, Abu Thur, Ibn Hazm and Shafi'ite sect allow *hajah* as legal justification in medical cases to consume unlawful sources of medicine.

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