Ethical Process and Medical Consideration on the Viability Limit of the Extreme Premature in Northeast Mexico

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Abstract

One of the big challenge of neonatologists is the decision on the viability and need of treatment of an extreme preterm newborn. Even with all the technological and scientific advances only preterm at 23 week of gestation are able to survive, but frequently with many complications. Neonatologist face an ethical dilemma and many of them put the decisions of initiate medical treatment as shared decisions between parents and practitioners. For many neonatologists in northeast of Mexico states the real viability limit is 26 gestational weeks. In this paper, we discuss the ethical principles involved in the decision of the limits of viability, the natural law paradigm, the deontology, the utilitarianism and the bioethics principles. The way this decision is constructed is not universal, because it is culturally influenced, and depends on experience, scientific and ethical knowledge. Many neonatologists do not know in deep the ethical principles needed to make these decisions and act more intuitively.

Introduction

In the early 80's, the survival of infants born before 27 weeks of gestational age (GA) was low(Hirata, 1973) Nowadays, the survival limit is equal or more than 22 weeks of gestation, with a survival rate of 60–70% in the best neonatal care centers (Garcia-Muñoz, 2015). If we consider the birth weight, the viability limit is 400g. Less than that will produce a viability rate near to 6–12% (Berger, 2017). Even, the medical advances had lowered the preterm mortality, the viability limit need to frequent review. Born with a GA of 23 to 25 weeks, impose great uncertainty on survival in Mexico, probable a 50% rate, with high risk of neurological and systemic complications (Pofit,2010).

The reasons to determine limits of viability are the high mortality, high morbidity, enormous physical suffering of the neonate, high degrees of parental stress and the high medical cost. The viability limit can follow international guidelines, but need to local definition in order to give guidance the neonatologist and give patients the best treatment possible.

In order to set the viability limit ideally we need a team of the following parties: the hospital governance, practitioners, nurses, parents and maybe other civil society actors. The analysis need to consider the bioethics principles of no-maleficence, beneficence, autonomy, justice in the right context. There are different ethical paradigms and plural perspective to deal with these delicate issues.

In the neonatal care centers of Monterrey there are not enough statistics on the survival of preterm with less than 25 weeks of GA and it is not always possible to extrapolate the experience of United States or European countries to the local settings. In addition, we previously researched the opinion on these topics in the local neonatologist of the city and there was no general consent. This preliminary information reflects the reality of actual local practice, and the protagonist role and leadership that practitioners exert on the viability limit establishment and is the key objective of this paper.

Medical Background

Premature babies represent 10% of newborns and is a frequent cause of morbidity and mortality. In recent years, the rate of prematurity (1,500g or less) has risen along with the medical complications. Preventing prematurity has not been an easy task, and still a big area of opportunity (López de Heredia Goya J, 2018). The incidence of prematurity has several causes: maternal sickness, obstetrics and gynecology problems, fetal causes, socioeconomic causes, fertility treatments with multiple products and iatrogenic care (García-Alix Pérez, 1999).

The survival rate of preterm neonates has improved substantially in the last 50 years. These advances came with collaborative work of neonatologist, perinatologists, trained personnel, new equipment, new treatments and the growing knowledge of the extreme premature physiology. One of the reasons of the successful management of premature newborns has been the homologation of specialized treatments and the use of prenatal corticosteroids. One of the previous goals has been to reduce the morbidity related to surfactant deficiency and renal immaturity. Now the new goals also include the optimum development avoiding neurologic complications. Sometimes neurological complications might not be evident in the first years of life, but until cognitive and motor skills become defective in the school age.

Neonatologists need to establish GA to predict mortality and morbidity, which vary between GA. For example, in Mexico a newborn with 27 weeks of GA will give the neonate good possibilities to survive, but with uncertainties of a good future neurocognitive functioning. Therefore, there is a need to assess the quality of life and long-term effects.

Determining the quality of life of the neonate is difficult for parents. They need to reconcile two concepts: doing everything in their power to promote their offspring survival, a human instinct, and on the other hand they need to consider the possibility to go against this instinct in order to avoid a nonsense and a dependent life, full of body damage. The background of parent's decision came from their religious beliefs, personal experiences, family beliefs, social expectations, socioeconomic status, educational level and ethical principles.

Because the complete set of adverse neurodevelopmental outcomes are not in the general population knowledge, some neonatal care centers accept parental consent for treatment only if they are well informed. In the appropriate cases, parents need information about the futility of treatment and about medical intervention with no qualitative and quantitative benefits.

Seri et al, discuss in his paper the opinion of several authors, considering neonates with less than 23 weeks of GA, with adequate weight for gestational age, or with birth weight less than 500g, with very little possibilities to survive at the short term and to a 6 month-period (Seri I, 2008).

Birth weight had been one of the most important factors calculating preterm viability and risk of mortality, but because some neonates can be small for gestational age, the gestational age is a better predictor of morbidity and mortality.

The objective of this paper is to identify the criteria for viability limit in the neonatology practitioners of Monterrey, Nuevo Leon, Mexico, and to discuss the ethical arguments they use.

Methodology

The objective of this paper need a quantitative and qualitative approach that combine tree aspects: medical-scientific approach, social sciences approach and ethical approach. We used true and false questionnaires, Hierarchical questionnaire with Likert Scale items, and open questionnaires where answers were coded for analysis.

For the factual approach on viability limits, we selected 41 neonatologists with actual public or private practice in the metropolitan area of Monterrey, Nuevo Leon. They answered two questionnaires and a survey. The General questionnaire included 15 items focused on their actual experience on extreme premature (26 weeks GA or less than 500g) and their knowledge of the bioethics principles. The Hierarchical questionnaire: was intended to grade in a 1 - 6 scale , from the most important to the less important items about the neonatal limit of viability The Open questionnaire included 3 questions about motivation to start or not the medical treatment to an extreme premature (26 weeks GA and less than 500g)

We conducted the study according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of the Master program in Ethics form the Universidad de Deusto in Bilbao, Spain.

Data recorded as a group, to maintain anonymity and confidentiality, and the intended use of the collected data was strictly for academic and scientific purposes. For the statistical analysis, we used descriptive statistics using STATA ver. 15 (College Station, TX)

Results

A total of 41 neonatologists (34% of the registered and active neonatologist of the city) and last year neonatology residents answered questionnaire and survey from September 1 to December 30, 2012.

The General questionnaire

The first question states that preterm neonates born with 25 week of GA might experience good survival possibilities and low neurologic sequels. Most of the respondents (70.7%) reported low survival and frequent neurologic sequels in their practices.

Question 2-4 explore if the practitioners had decided on the viability limits. A total of 80% treated preterm neonates of 23 weeks of GA or less than 500g birth weight and 87% had to decide to initiate or not medical treatment.

Question 5-7 explore the preference of practitioner to assign protagonist role in the decision of survival limits and treatment initiation within the different decision's parties. Most of the respondents expressed is responsibility of neonatologists and they should decide.

In question 8, a total of 83% answered that the limits of viability are an ethical dilemma.

Question 9-12 explore the practitioners' knowledge of the bioethics principles, and the application of these principles in the viability decision.

The no- maleficence is the less known and the autonomy principle the most known. About 34% responded that parents had the responsibility of the decision to initiate treatment in an extreme premature, and most of them (82%) based their decision on the autonomy principle.

Question 13 explore if neonatologist is obligated to preserve the live as a principal outcome when treat preterm of 25 weeks of GA, (11) 31% answered they are not obligated.

Question 14 explore if they rely on the utilitarian paradigm, most of respondents preferred the less suffering and highest wellbeing.

Question 15 explore if they recognize the civil society, as a moral agent, should be involved the viability limit decision. From the questionnaire, 56% of neonatologist will consider the civil society opinion.

The Hierarchical questionnaire

In this questionnaire, option 1 is the most important and option 6 is the less important.

In Table 2, the consideration of the future quality of life received the highest acceptance 2.28; followed by the opinion that parent should decide on viability and the neonate right to live, 2.82 and 2.84 respectively. The excessive medical cost and medical pride to make neonate survive was not favored as an option to set the survival limit, 5.10 and 5.35, respectively.

Open Question Survey

The positive motivation to initiate or keep treatment in an extreme preterm was absence of grade III and IV intraventricular hemorrhage, general good evolution, parents with enough resources for medical cost, absence of malformation, genetic or severe cardiac defects, severe prenatal infections and any disease incompatible with life.

Some mentioned that motivation to keep treatment was certainty about neonate's maturity, if family agreed with the treatment, advances in the initial treatment or signs of clinical stabilization. The degree of information obtained is mainly informative and their perspective is multifactorial. Most of them place the limit of viability on more than 26 week of GA.

Some will continue the treatment even if the patient is below the limit of survival, if they have the parental permit, if they have enough financial resources, if the neonate is the only child, if the mother had frequent abortion, or for the sake of saving the life of the neonate. However, some of these reasons might be ethically questionable, because they can be considered therapeutic obstinacy. These answers reflect, as mentioned before, that respondents do not differentiate between ethical, medical and sociological reasons. The given ethical reasons relate to the autonomy principle, to respect life and dignity and to justice principle, but there is not enough clarification of these principles between neonatologists in how they apply the principles in the decision process.

Other reasons to keep the treatment in the extreme premature included certainty on the neonate maturity, family's approval, good initial results of early treatment, and the recognition of signs of improvement. Most of respondents set the limit of viability in 26 gestational weeks.

Only 24% of respondents say that decision to keep the neonatal treatment might rely on the presence of complications and the parental permission. Other answers for conservative treatment included neonate as their only child, parents with frequent abortions and for the sake of saving the neonate life. Most respondents referred 26 gestational weeks as the viability limit.

Discussion

Most of neonatologists (87%) had decided on viability limits on their own knowledge, with plenty of discretionary authority given to them by public or private hospital directors. This fact underlying the importance of the issue and the need of neonatologists to have proper medical and ethical training for this decision making process. At this point, we need to analyze the moral pertinence to have more parties involved in this decision (Hernández-Martínez, 2011).

Most of neonatologists embrace the ethical principle of the Hippocratic paternalism, where doctors know what is best for his patients, and assigning responsibility on the limit of viability only to practitioners. However, more debate should exist on the right of parents to participate on the viability decision. Parents need enough truthful information, in a clear and complete way. This is the autonomy principle that empowers parents to participate on the viability decision, but with social controls to avoid neonate damage, when they had no capacity to make this decision (Etxeberria, 2012).

Most of neonatologists consider the viability limit an ethical dilemma, and because of that they should be supported by a specialized ethical team. Even that local hospitals have an ethical committee, the viability limit is not always consulted with them, unless there is conflict between practitioners and parents.

Very few of the respondents recommended that Hospital's rules include the viability limit. Probably because many of them considered that there are not enough normativity or even interest on this issue, in the health care administrators.

It is true that such a decision should not rely only to the Institution, but the institution's administrators should provide enough support, probably through the Ethical Committee, to work collaboratively with practitioners and neonate's parent to define rules for this decision (Arnaez J, 2017). In other care centers a prenatal ethics consultation team become available 24h and includes an obstetrician, neonatologist, a specialized nurse and an ethic expert (Dirkensen, 2017).

It is worth to mention, that the simple acknowledgement of the ethical principles, do not imply full knowledge of its deeps and interpretations. (Extxeberria, 2011)

In this process, there is a need of a factual approach, including international, national and local experience and expertise. For example, the best neonatal care centers reported and preterm neonates with less 22 weeks of gestation or less had no chances to survive. This posture relies on the immaturity of the physiologic process of the fetus and the experience of near 100% mortality of these neonates in the first hours after birth (Ceriami. 2018)

Taking into account these facts, only 9% of neonatologist considered that the limit of survival is 24 gestational weeks, the others preferred to set 25 gestational weeks as the limit. With respect of birth weight, most considered 500 g as the limit of viability, but the birth weight is not a good as the reference for the survival limit because it cannot estimate precisely the degree of maturity.

There are some extreme postures like the Swedish Consensus Guidelines (2016), were the viability limit is set to 22 gestational weeks and they include the opinion of parents (Domellöf, 2018). Most preferred the viability limit of 25 gestational weeks and more than 600 g of birth weight, with and expected survival of 60–70% and 50% chances of not having severe neurological sequels like cerebral palsy, mental retardation, visual impairment, deafness and other neurodevelopmental problems. This view promotes the “procreative asymmetry” that tries to denude neonate from his moral status, but violates basic principles of justice and shared decision-making (Kukora, 2017).

Neonatal care centers of Monterrey, as in many cities in Mexico, had this ethical dilemma on the viability limits without a governmental norm or well-accepted universal guidelines. Most of these decisions rely on the individual practitioner's criteria that take into account the personal knowledge the desire to preserve life and the personal commitment to the wellbeing of the neonate and sometimes the ethical fundaments.

Between 60–70% of neonatologist referred to know the bioethics principles, probably not enough to solve the definition of limit of viability. The majority, 87% of neonatologist had decided the limit of viability on his own means or knowledge, urging the need of formal training in ethics. Garcia-Muñoz recommend that neonatologist need to have actualized knowledge of local, national and international morbidity-mortality rates of neonates and the most recent guidelines for extreme premature (F. García-Muñoz Rodrigo, 2015). Neonatologist dealing with the limit of viability must have support from a specialized ethic team with enough credentials in bioethics or in fundamental ethics. From the questionnaire, 48% of them said neonatologist must decide on the viability limit, and 24% that the parents should decide. Very few of them

said that was a shared decision. The dialogic principle will imply to have a shared decision between practitioner, parents and hospital administrators. In addition, there is a need to respect local beliefs or customs that sometimes are scarcely flexibles (Alwadaei S, 2019). A final scenario will include the no-consent posture and the need of judiciary meditation to settle down the decision (Oehmke, 2019).

One of the principles tested in the survey was the respect of life with its own rights. However, most neonatologist believed that there is no obligation to preserve life, without reassurance of good quality of life. The life of a neonate cannot be seen only in his need of quality of life. According to the Natural Law, the final goal is related to the human nature, not only in the accomplishment or development of human capacity, but because his essence. Deontologist teach that dignity is inherent to humans, not disturbed by accidental circumstances (Bucher HU, 2018).

In the extreme premature, one can choose to direct the course of action by the respect of life, with the support of science. From the 23 week of GA, there is a chance to survive and is the practitioner's responsibility offer treatment and try to avoid the medical complications.

For many religions, the ultimate goal of patient is to reunite with the Creator. If the practitioner actions align to this goal is in consent with the neonate's parents, treatment can be offered to the extreme premature neonate even at 23–25 gestational week. However, the argument of the naturalistic ethics with religious implication should not be imposed. All decisions should incorporate at least a minimum of respect to human rights, and its interpretation should include authentic social dialogue.

In the deontologist paradigm based on Kant, life deserve unconditional respect, but life in the person set the discussion on what moment the embryo or fetus can be considered human (Albersheim, 2020).

Question 14, showed the conflict of the utilitarianism model against the natural law, and most of neonatologist chose the wellbeing of the living being over the life itself. There is a need to create a debate with these protagonists and review each of the models and their backgrounds. Some of them will link this utilitarianism model with the principle of no-maleficence, but only if the interpretation is led by the avoidance of pain.

In the Hippocratic tradition, the no maleficence principle means no harm to the life as expressed in the natural life. Others can interpret the principle as no damage to the human dignity, different to do not produce pain. We perceived some confusion of the ethical principles and neonatologist need more clarification of concepts while dealing with the no-maleficence principle.

Half of the neonatologist thought than decision on initiate treatment or limit of viability should include civil society, as moral person. This goes beyond the personal directly involved in the neonatal care. This incorporation of more decision takers deals with justice and not only with wellbeing, supporting the paradigm of dialogic or discursive ethics. Habermas said that this paradigm is well goes aligned to the deontology Kantian paradigm, but not aligned to the natural law and utilitarianism paradigm (Sauri, 2011). Neonatologist must incorporate these arguments while deciding on limit of viability.

According to the natural law if the embryo has the inclination to preserve life, life must be respected. Extreme premature has the same dignity of other neonates and life should be maintained until he (or she) can develop its potentiality. (De Martini, 2016) Based on this approach, the elimination of a human being in the beginning of postnatal life is murder. In the case of an extreme premature is not licit to accelerate death, only by the fact of technical immaturity, the anticipation of excess pain and suffering or the bad prognosis for neurological development.

The fundament of his paradigm is human dignity, considering the person as its own end. Each of the extreme premature are its own end with inherent dignity and respect. The neonate potentiality should direct the decision to initiate treatment if there is at least a small chance of survival. In other words, survival or postnatal complication of a medical treatment do not affect the neonate's dignity. One can argue, when is the moment dignity starts? The solution of this problem consist on considering treatment from the gestational week in which science and medical advances showed effectivity. In the world best neonatal care centers, the set point is 23 gestational weeks, but in our city of Monterrey, probably 25 gestational weeks is more realistic.

The utilitarianism paradigm holds the best good or beneficence should be the drive. Nevertheless, this paradigm does not contemplate the inner human being importance, only the result and survival with the less possible sequels. In the standards of the neonatal care of Monterrey, a set point for survival with the less sequels possible might be 30 gestational weeks. In this sense, in not adequate to treat premature as things or products, and to dictate that a life with no good quality is not good. (Mills, 2020)

The utilitarianism principle also supports what is best for all for the majority of people, as society, benefits in the saving of economic resources, because the survival outcome is very difficult and costly. In this sense, they might argue that resources are better spend in the generation of pleasure and satisfaction instead pain and incapacity. This paradigm goes against the natural law, Deontology principle, and divine law (in Christian and other religion view). In fact, this principle might represent the emancipation of the morality values or maybe a characteristic of a postmodern ethics. (Sygmunt, 2009) If this decision is followed International practice guidelines impose a minimum of palliative comfort care according to parental and practitioner discretion (Cavolo et al 2019) (Dirksen et al. 2020).

We prefer to honor the respect of life and dignity against the pragmatism. The utilitarianism model applied to the limit of viability propose no treatment for neonates with certainty of good development or to parents if he (she) become destabilized. This view might drag the limit of survival to the point of survival with no sequels. Science provided evidence on the suffering while enduring medical treatment, some might think not allowing the suffering of an uncertain future. So let neonate died without pain is within the utilitarianism model. It the view of the greater good for the society, the utilitarianism model will discourage to expend such a great cost for the suffering of the extreme preterm neonates, and will try to derive more resources for the pleasure such as healing for the many. Since the extreme premature suffers it will be better not allow it

After the above arguments, it is appropriate to say that most neonatologists had no formal ethical training, so they need to decide on the viability limit under the pressures of other professionals, family, and religion and very importantly on the availability of economic resources. There are some neonatal care centers in the city that do not have enough budget to follow the natural law and deontology principles, so they just follow the easy path, that is the utilitarianism.

There are neonatal care units that do not have enough budget to do what suggests the natural law and deontology, so they follow the economic pragmatism and utilitarianism and many preterm do not receive the chance to survive.

It is very common that in ethical medical dilemmas, science has the last word, but this is not entirely right. Because of the need of deep ethical analysis from different perspectives in order to solve such a complex problem. When listening civil society, this act became a good democratic exercise, and when the civil society is more involved the better construction of social tissue.

Conclusion

The definition of limit of viability is an ethical dilemma involving practitioners, parents, patients, government and civil society. For this decision neonatologists need medical knowledge and analysis of the ethical paradigms. Neonatal science should be the starting point to solve the dilemma. Most of the neonatologists in this study faced this ethical dilemma by themselves without knowing the ethical principles to solve the problem. They set the viability limit in 26 weeks of GA, two weeks above the limit of many other neonatal care centers.

The natural law defines the human nature in its link with the Supreme Being and defend the value of life. The extreme premature should receive treatment since the early possible week that will derived in survival and then fulfill its ultimate end.

The deontological view propose to defend human dignity as its own end. The defense and respect of life may allow the person to reach its potentiality, reason, liberty and autonomy.

The utilitarianism principle propose to avoid pain, to look for pleasure and the more happiness for the majority of people. In this view, it is not good for the neonate to precipitate pain without guaranty of an optimum result. The end in itself is pleasure and happiness, not the life and dignity of the neonate.

It is necessary to do more sociologic studies to try to clarify the no maleficence and beneficence concepts. Neonatologists should have form training in fundamental ethics or bioethics. In addition, there is a need to work together with the ethics committee in each hospital for a collaborative definition of the survival limit. The process of defining the limit of viability is difficult and must include collaborative work of ethical specialist, practitioners, civil society and government, based on proved science.

Declarations

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