

AT THE LIMITS OF VIABILITY: A CLINICAL AND ETHICAL ISSUE

NA GRANICAMA VIABILNOSTI: KLINIČKI I ETIČKI PRIJEPOR

Giampaolo Mandruzzato

Review

Key words: fetus, viability, growth restriction, very low birth weight newborns

SUMMARY. Fetal/neonatal viability, the survival rate and »intact« survival rate of very low gestational age fetuses resp. of very low and extremely low birth weight newborns are presented. The mode of delivery i.e. the cesarean section in maternal and in fetal/neonatal indications, in which the fetus cannot give an informed consent is discussed.

Pregled

Ključne riječi: fetus, viabilnost, zastoj rasta, djeca vrlo niske porodne težine

SAŽETAK. Prikazani su fetalna i neonatalna održivost, preživljavanje i »neoštećeno« preživljavanje u fetusa vrlo male gestacijske dobi odnosno u novorođenčadi vrlo niske i izrazito niske porodne težine. Razmotreni su način rađanja, tj. carski rez kod maternalnih i fetalnih indikacija, u kojima fetus ne može dati obavijesni pristanak.

Fetal viability has been defined as »the ability of the fetus to survive ex utero with full technological support through the neonatal period and into the second year of life, during or near the end of which independent moral status comes into existence«.¹ Based on available clinical results the same authors suggest that viability should be considered at a gestational age of 24 weeks or more.² However, it has also been pointed out that the term »limit of viability« should be removed from our vocabulary as it is clinically and ethically simplistic.³ In fact, the outcome is not dependent only on gestational age and/or birthweight but also on other possible fetal complications. Moreover, the characteristics of »full technological support« to the newborn can significantly differ between countries as well as centers within a country. It should also be kept in mind that varying attitudes toward neonatal intensive care greatly influence the survival rate at two years of age, and the prevalence of disabling cerebral palsy among survivors.⁴ In fact, when more aggressive management was applied, the survival rate and the prevalence among survivors was higher as compared to more conservative treatments. This observation introduces the concept of »intact survival«, instead of the crude figure of the survival rate alone. Both neonatologists and obstetricians, when faced with patients at the limits of viability (mainly because of large prematurity), they must take into consideration the clinical and the ethical aspects of this issue.

However, when making decisions at the limits of viability, obstetricians can be faced with far more complex challenges in comparison with neonatologists. The neonatologist is required to provide the best possible care to the critically ill newborn, but can consider the choice between intensive or compassionate care, in agreement with the parents. In contrast, the obstetrician, being the doctor of both the mother and the fetus, has to cope with

a very complex situation if a cesarean section (CS) is indicated. If the indication for CS is maternal (placenta praevia, abruptio placentae, eclampsia, etc.), the decision is straight forward to save the mother's life. The problem arises if the CS is required for fetal compromise like hypoxia in a IUGR fetus, when the only efficient management is delivery of the fetus to remove it from the adverse maternal milieu.

In simple terms, this means performing a surgical procedure on the mother (the first patient) to presume a benefit for the fetus (the second patient). Following the principles of beneficence for the fetus and respecting its autonomy, it is clear that the second patient (the fetus) cannot be asked to give informed consent for the treatment. As a consequence, exhaustive counseling in terms of survival and intact survival probability based on the best available evidence should be given to the parents, particularly the mother. This is a difficult situation, as clinical randomized trials comparing different managements for this particular condition are lacking.

There are many factors influencing early and late outcome which should be taken into consideration, among which gestational age and birth weight are the most important.

Gestational age

The concept of viability dependent on gestational age at birth has changed in the last twenty years due to improvements in perinatal care. In 1984 Milligan et al.⁵ have observed a survival rate more than 50% at 25 weeks and above, and have indicated that intervention for fetal indications was justified. One year later in 1985 Kitchen et al.⁶ reported a survival rate of 20% at 25 weeks, and in 1986 Yu et al.⁷ published a survival rate of

25% at the same gestational age. In a short period of time (three years) conflicting results concerning the survival of premature infants at lower limits of viability have been presented by three major research centers. About 15 years later the situation is not any clearer. In 1999 Bottoms et al.⁸ have reported the neonatal mortality rate and the intact survival rate in a large study. The neonatal mortality rate has declined to 20.9%. Unfortunately, despite the fact that survival rate increased significantly (up to 80%), the »intact« survival rate remained at only 35.8%. Similar results were reported in 2001 in the study by Chan et al.,⁹ who found that at 25 weeks survival rate was 76%, but only 32% of the survivors were without major morbidity.

Looking at lower gestational ages, the outcome considering survival and intact survival rate were even poorer. In 1999 it was reported by Hussain¹⁰ that there are not survivors beyond 22 weeks and 3 days, with unfavorable outcome (death or major disabilities) at 23 and 24 weeks occurring in more than 85% of newborns. Similar results were found in the year 2000 by EL-Metwally et al.¹¹ who considered only survival without morbidity. The survival rate at 22, 23, 24 and 25 weeks were 4,6%, 46%, 59% and 82% respectively. Such information which does not take morbidity among survivors into account could be one of the reasons for gynecologists to perform active management. Unfortunately, in the recent study¹² it has been shown that the willingness to perform cesarean section at 23 weeks has increased from 15,9% in 1995 to 28,2% in 2000, which was not associated with the better neonatal outcome. Moreover, it has also been recently reported that aggressive obstetrical and neonatal management between 23 and 26 weeks was not associated with a better survival rate, and that acute and chronic morbidity among survivors did not change substantially.¹³

Birth weight

According to the birth weight (BW) newborns at the lower limits are classified as low birth weight if BW is less than 2500 g (LBW), very low birth weight if BW is less than 1500 g (VLBW) and extremely low birth weight, when BW is less than 1000 g (ELBW). From the practical point of view it is easy to evaluate outcome according to the BW, although its clinical significance is limited. Low birth weight neonatal population is not homogeneous in terms of their gestational age because it includes preterm and growth restricted newborns. Moreover, the papers reporting the management and outcome of VLBW and ELBW are rarely taking into the consideration infant gestational age, which means that criteria for defining »viability« only on the estimation of birth weight are not appropriate.

Fetal compromise

It has been shown that fetal compromise adversely affects the outcome at the limits of viability.¹⁴ In the group

of 142 babies born between 23 and 25 weeks, 43 have presented at least with one sign of fetal compromise like major congenital anomaly, congenital sepsis, chronic intrauterine infection, intrauterine drug exposure, congenital anemia, severe IUGR, fetal acidemia, cardio-respiratory and neurologic depression in the delivery room. The majority of these conditions are detectable before birth. Therefore an accurate evaluation of fetal conditions is mandatory before making the decision considering the way of conservative or more aggressive treatment.

Mode of delivery

As it was mentioned before, if the indication for CS is maternal, than the obstetrician has an obligation to perform the treatment in the best interest of the mother's health. The choice is more difficult when the possible indication for CS is fetal. The most common situations in which CS can be considered as an option for improving neonatal outcome at low gestational age are fetal hypoxemia and breech or other malpresentation. These indications should be analyzed and discussed separately. Fetal hypoxemia is present in 30 to 35% of IUGR fetuses, particularly in ELBW fetuses. The only available treatment delivery and therefore very often indications for CS should be discussed. Among factors which should be taken into consideration the most important are gestational age, estimated birth weight, gender, absence of fetal malformations and the characteristics of the fetoplacental hemodynamics.¹⁵ In fact when absent or reversed end-diastolic flow (ARED) are observed it is necessary to distinguish between end-diastolic flow area (EDFA) and reverse flow (RF). In the last condition the prevalence of severe handicaps among survivors is more than 35%.¹⁶

In the case of breech presentation and prematurity, the most important issue of making the decision to perform the CS is to reduce or to avoid birth trauma, which can possibly cause neurological damage or impairment. According to the available data this goal could not be achieved by delivering the ELBW at risk by CS.^{17–19} In fact it has been shown that CS in breech presentation of VLBW and ELBW does not improve the outcome if looking at the intact survival. It should be remembered that in tiny premature infants the majority of the causes of cerebral palsy are the consequence of prematurity by itself.

Conclusions

The concept of fetal viability is unclear and strongly dependent on ethical, moral and religious personal belief. Therefore it is very difficult or almost impossible to make universal guidelines for the management of extremely premature fetuses and infants. The bulletin of American College of Obstetricians and Gynecologists »Perinatal Care at the Threshold of Viability« edited in September 2002²⁰ offers Recommendations of Level A

which are rather imprecise, mainly focused on the importance of the information to the family. Also the present scenario is not encouraging as it has been shown that in VLBW the rate of mortality, pneumothorax, intraventricular hemorrhage (IVH) and severe IVH has declined till 1995 but from 1995 to 1999 there were no significant changes in the incidence of IVH, while the incidence of pneumothorax increased.²¹ Therefore the ability for appropriate counseling of the parents concerning the treatment of infants at the limits of viability did not change in the last few years, and it is dependent on the local mortality and morbidity statistics for those tiny infants. Obstetricians should always remember that the parental perception of »good short or long term outcome« significantly differ compared to the doctors. Therefore the obstetricians should make any effort to understand the parents and to practice what they preach.

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Address for correspondence: Prof. Giampaolo Mandrizzato, Via del Lazzaretto Vecchio, 34123 Trieste, Italia, e-mail: mandrizzato@giampaolo@tin.it