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Magnetic resonance pelvimetry in breech presentation at term.

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Document Version

Publisher's PDF, also known as Version of record

Publication date:

1998

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Loon, A. J. V. (1998). *Magnetic resonance pelvimetry in breech presentation at term.* s.n.

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Chapter 7

Summary and conclusions

Summary

The first detailed description of the anatomy of the female pelvis was given by Andreas Vesalius more than 400 years ago, but it was not until the publication of Van Deventer's work more than 100 years later that physicians started to pay greater attention to the mechanism of delivery (Chapter 1). Numerous variations of instruments to measure the female pelvis have been invented since then, but none of them were adequate. X-ray pelvimetry banished all previous instruments about 70 years ago and has been in use ever since to approach fetopelvic disproportion. Manual pelvimetry does not conform to the standard, i.e. the detection of pelvic abnormalities, and especially the sensitivity leaves a lot to be desired. Ultrasound scanning has not been proven to be valuable either, the images are vague and usually not reproducible.

Existing data on pelvimetry strongly indicate that it does not have any significant prognostic value in cephalic presentation. In the case of very severe disproportion the policy is clear, namely caesarean section (CS), and in all the other cases a well-monitored trial of labour is acceptable in every way, as long as high- or mid-forceps delivery is not employed and only vacuum or forceps delivery is applied or CS if there are strong indications. Pelvimetry postpartum may be worthwhile in preparation for the delivery of an infant from a later pregnancy if the course of labour gives reason for this, such as a difficult (forceps/vacuum) extraction or CS due to poor dilatation.

In breech presentation the situation might be different: pelvimetry might help to select the best route of delivery. However, no prospective controlled studies have been performed to evaluate the outcome of breech presentation on the basis of the result of pelvimetry. Even in the few randomised trials that compared planned vaginal delivery to elective caesarean section, pelvimetry was used to exclude women from planned vaginal delivery if one or more pelvic measurements were contracted. These studies therefore relied on a selection parameter whose value has not been proven.

With magnetic resonance (MR) imaging a new method for pelvimetry became available. This technique makes imaging in multiple planes possible without the use of ionizing radiation. The first reports on the use of MR imaging for pelvimetry showed that the resolution of the images was very good and it was concluded that pelvimetry is a valuable tool in the management of breech presentation. However, despite the technical accuracy of this new diagnostic test, it does not demonstrate whether pelvimetry is worthwhile in breech presentation. In the studies reported on in this thesis, several aspects of the use of MR pelvimetry in breech presentation at term are discussed.

To evaluate the new method of MR pelvimetry, antepartum MR pelvimetry was performed on 10 women with breech presentation at term (Chapter 2). This was followed by postpartum pelvimetry with MR imaging to exclude any differences between antepartum and postpartum situations and with conventional X-rays, because X-ray pelvimetry has been the golden standard so far. There were no differences between the antepartum and postpartum situation except for the obstetric conjugate, which appeared to be somewhat longer during pregnancy (mean difference 0.5 cm). The clinical relevance of this difference is questionable and the only conclusion that can be drawn is that the generally accepted minimum X-ray values might be too cautious. Measurements with MR imaging appeared to be at least as reliable as those obtained with X-ray pelvimetry, while the contrast of the MR images was superior. The mean interspinal distance with X-ray pelvimetry was 0.5 cm smaller, while the mean intertuberal distance was 0.9 cm larger than with MR pelvimetry. An explanation for the differences might be that X-ray pelvimetry in the antero-posterior view is not always reliable. In many cases, this X-ray image was not very clear. However, the differences were so small that it was considered acceptable to apply the existing X-ray image values that are acceptable for vaginal delivery to the MR images. The study showed that MR pelvimetry is technically accurate and that it was justified to assess its value for the clinical management of breech presentation at term.

To assess this value, MR pelvimetry was performed in a randomised controlled trial on 235 women with a singleton pregnancy, a gestational age of ≥ 37 weeks and a fetus in breech presentation (Chapter 3). Exclusion criteria were an estimated fetal weight exceeding 4000 g, hyperextension of the fetal head, a known fetal structural defect, multiple pregnancy, a known pelvic or uterine abnormality, previous fetopelvic disproportion or planned elective CS for reasons other than the suspicion of pelvic contraction. Multiparity was not an exclusion criterion as long as the referring obstetrician had doubts about a vaginal delivery because of a previous pregnancy that had ended in a CS, a low birth weight infant and/or a difficult labour. The main outcome measures were the elective and the emergency CS rates and the early neonatal condition. Directly after pelvimetry, randomisation was done to obtain a study group

pelvimetry became possible without the use of X-rays. It was concluded that MR pelvimetry was not demonstrably superior to conventional X-rays. However, the results of the studies reported on breech presentation at

pelvimetry was performed (Table 2). This was followed by any differences between conventional X-rays, there were no differences for the obstetric history (mean difference was not statistically significant and the only difference was that the minimum X-ray values were at least as good as the MR pelvimetry was 0.5 cm better than with MR pelvimetry in the study group. The X-ray image was not considered acceptable for vaginal delivery to the study group. It is highly accurate and that the study group

randomised controlled trial at 37 weeks and a fetus with an estimated fetal weight of 3.5 kg. There was no fetal structural defect, no previous fetopelvic disproportion, no suspicion of pelvic contracture, and no referring obstetrician. The pregnancy that had a normal outcome. The main outcome was a healthy early neonatal condition. The study group

(n=118) and a control group (n=117). The pelvimetry results of the study group were reported to the women's obstetricians, whereas the results of the control group were not disclosed until 8 weeks postpartum.

The overall CS rates in the study group and in the control group were 42.4% and 50.4%, respectively ($p=0.24$). The emergency CS rate in the study group was 18.6% versus 35% in the control group ($p<0.01$). Considering only the women who were selected for planned vaginal delivery, the emergency CS rate was 24.4% in the study group and 41.4% in the control group. These differences could not be explained by the variables maternal age, parity, type of breech presentation, engagement of breech at MR pelvimetry and birth weight, because there were no statistically or clinically significant differences for these variables between the study group and the control group. Even after the 14 women with pelvic abnormalities in the category planned vaginal delivery in the control group had been excluded from the analyses, there was still a significantly lower emergency CS rate in the study group. In the control group, in comparison with the study group, relatively more emergency CS were performed in the category of women who had augmentation or induction of labour than those who had spontaneous onset of labour, and it was also remarkable that a prolonged first stage formed the reason for an emergency CS significantly more often in the control group than in the study group. It is likely that the obstetrician felt safer to proceed with the vaginal delivery in the study group. It has been suggested that too much reliance on the pelvimetry results could cause an increase in perinatal morbidity and mortality when other data such as estimated fetal weight, progress of labour and engagement are not taken into account. In the study described in this thesis, there were no major differences in the early neonatal outcome between the respective categories in the study group and the control group. In contrast, the significantly lower Apgar score of the infants born vaginally in the control group of women who had pelvic abnormalities, indicates that not using the pelvimetry data could put the fetus at risk.

Almost 50 years ago, a warning was published that the introduction of X-ray pelvimetry had caused more harm than good in the intelligent management of pelvic contraction, partly because of the faulty interpretation of pelvimetry films. To avoid the perpetuation of this error with MR pelvimetry, all the pelvimetry measurements were evaluated and the intra- and inter-observer variability were investigated (Chapter 4). For each participant 7 sagittal images were constructed around the midline from 3 transaxial scout images and 15 oblique-coronal images were constructed from the median sagittal image. Analysis of all 235 women showed that 3 sagittal and 11 oblique-coronal images were enough to perform all the measurements. Together with the use of the newest generation of MR systems, this will reduce the total scanning time markedly and we estimate that the whole procedure of MR pelvimetry will not take more than 10 minutes. Analysis of all the measurements of the 235 participating women showed that 35 women (14.9%) had one or more abnormal pelvime-

try parameters: 15 women had one or more linear measurements that were too low, 17 women had abnormal angles (because of a transitional vertebra and/or assimilation of the last lumbar vertebra with the sacrum) and 3 had both abnormal angles and low linear measurements.

Intra- and inter-observer variability investigations were conducted on 72 randomly selected women from the 235 participants (36 women for each test). All repeat measurements were done with blinding against the initial results. The correlation coefficient, the coefficient of variation and the limits of agreement and possible systematic bias were calculated for each measurement. All mean differences were small (less than 2 mm), except for the interspinal and intertuberal distances (less than 4 mm). The correlation coefficients of all measurements were close to one ($p < 0.001$), while the coefficients of variation were small (1.6 to 4.5%). The limits of agreement were small for all sagittal measurements (circa -5 to 5 mm), but relatively wide for the measurements in the oblique coronal plane (circa -10 to 5 mm). The correlation coefficient and the coefficient of variation appeared to be inappropriate instruments to assess the reproducibility of MR pelvimetry. Only the calculations of the limits of agreement for each measurement enabled us to see that some intra- and inter-observer differences might be clinically important. Knowledge of these limits of agreement should be taken into consideration by radiologists and obstetricians and in the case of borderline results, the measurements should be repeated and the radiologist and obstetrician should confer.

Whether a new diagnostic tool such as MR pelvimetry should be implemented in clinical practice is not only a medico-technical issue, but the views of pregnant women with breech presentation at term about vaginal breech delivery and CS and their opinion about the high-technology diagnostic tool MR pelvimetry are equally important (Chapter 5). A questionnaire and a 20-scale state anxiety inventory were administered to the women who participated in the randomised controlled trial before and after pelvimetry and at 8 weeks postpartum. The results of 226 (96.2%) out of the 235 women were available for analysis. Fear of a vaginal breech delivery was reported by 78% of the women and the majority of them mentioned the risk for their child as the reason for their fear. A CS was a frightening prospect for 58% of the women; an elective CS was preferred a priori by 19.5% of the women, but only 4.6% of the women for whom a vaginal delivery was planned actually asked their obstetrician to do an elective CS instead. So the majority of women in our study with breech presentation at term did not prefer an elective CS to a planned vaginal delivery despite their fear of complications during a vaginal delivery. Therefore, in contrast with what has sometimes been recorded, most of the women in our population did not exert pressure on their obstetrician to perform a CS to deliver their breech presentation term infant.

The mean state anxiety level before MR pelvimetry was higher than afterwards ($p < 0.001$), reflecting heightened anxiety in anticipation of the examination. The

scores were close to the mean anxiety score found in groups of healthy women of the same age. There seemed to be a certain amount of relief after a slightly heightened level before the examination. The vast majority of the participants rated the examination as positive. Spatial constriction and noise were most frequently mentioned as negative features. The results indicate that claustrophobia was not a major problem, most likely because the duration of the examination was short. As the actual scanning time will be reduced further with the newest generation MR systems, the problem of claustrophobia will probably be reduced even further.

Introduction of MR pelvimetry or using it to replace other forms of pelvimetry implies extra financial cost (Chapter 6). As there is no existing tariff for MR pelvimetry, an integral cost analysis was performed: the cost of the MR staff and the MR system, the cost of medical/technical and secretarial supplies, the cost of household and accommodation and the overhead cost were calculated. The total cost was Dfl 388.00 per examination, which was low in comparison with the existing tariffs of other MR examinations. The cost of the MR examinations was determined for 57.5% by the cost of the MR system itself. The use of the newest generation of MR systems will markedly reduce the cost per examination, because the purchasing and maintenance cost are lower and the total individual scanning time is shorter.

For the assessment of the cost of vaginal delivery, emergency CS and elective CS in the study group and the control group, existing tariffs and fees were used. The results of 220 (93.6%) out of the 235 women who participated in the randomised controlled trial and also returned the questionnaire 8 weeks postpartum were available for analysis. There was no statistically significant difference in the cost between the respective categories of the study group and the control group. Calculated for the study group and the control group, the mean overall cost for a CS was Dfl 5,499.00 higher than for a vaginal delivery (median Dfl 5,596.00) ($p < 0.0001$). Assuming 200,000 deliveries per year in the Netherlands of which 2.5% breech presentation at term, the cost of MR pelvimetry would be Dfl 1,940,000.00. A reduction in the overall CS rate in breech presentation at term of $\geq 7\%$ is enough to compensate for the cost of MR pelvimetry. With the newest generation of MR systems, a reduction of $\geq 5.5\%$ would be enough to compensate for the cost of MR pelvimetry. Our study showed that the mean and median cost per patient in the study group, the use of MR pelvimetry included, were Dfl 321.00 and 654.00 lower, respectively, mainly caused by an overall CS rate that was 8% lower, but the difference was not statistically significant. On the other hand, if pelvimetry in breech presentation is considered worthwhile, the cost of MR pelvimetry certainly does not form a reason not to introduce it or to continue the use of X-ray pelvimetry.

Conclusions

In almost all previous studies on the policy for breech presentation at term, (X-ray, CT or MR) pelvimetry formed part of the selection procedure for a trial of labour, despite the fact that until now, no prospective studies were available which examined pregnancy outcome as a function of the pelvimetry results obtained before breech delivery. The dilemma of whether elective CS should be preferred to a trial of labour has not been solved by the studies described in this thesis, but it has solved the pelvimetry dilemma in breech presentation at term: it is possible to make better a priori selection of the route of delivery without increasing the overall CS rate by using MR pelvimetry. Although too much reliance on pelvimetry results alone could cause increased perinatal morbidity and mortality, the results of the study in this thesis indicate that if other factors are taken into account, the neonatal outcome is not compromised; on the contrary, not using pelvimetry data in a trial of labour puts the fetus at risk. Women's opinions about MR pelvimetry were generally positive and claustrophobia was not a major problem. MR pelvimetry should be preferred to X-ray pelvimetry, because of better image contrast, the possibility of imaging in multiple planes and the absence of ionizing radiation; the cost of MR pelvimetry is relatively low and certainly does not form a reason to continue with X-ray pelvimetry.

A caveat, however, is also needed. Before starting to use MR pelvimetry radiologists and obstetricians should fully acquaint themselves with the technique and determine their own intra- and inter-observer limits of agreement. A pelvimetry protocol for (contra-)indications, standard adjustments and image planes is required. Particularly in breech presentation at term, there is pressure to give nearly instantaneous service, a waiting period of three days at the most is acceptable. Computer based information transfer can be extremely useful for this purpose.

At many institutes the CS rate in the case of breech presentation at term is increasing, despite the fact that there are still no appropriately sized randomised controlled trials that answer the question of whether planned vaginal delivery or elective CS is the better choice and also despite the fact that increased maternal morbidity is probably an inevitable consequence of CS. A vicious circle arises: less experience with vaginal breech delivery means fewer appropriately qualified obstetricians to deliver a term breech vaginally; this will result in an increase in the CS rate or, in the worse case, in an increase in adverse neonatal outcomes after vaginal breech delivery. If one considers that the vaginal delivery of any breech is unacceptable, than the question of whether pelvimetry is worthwhile is totally irrelevant. In that case, the studies in this thesis are also irrelevant. However, as long as the question of which is better - planned vaginal delivery in selected cases or elective CS - remains open for debate, MR pelvimetry should form part of the selection procedure for a planned vaginal delivery.



Samenvatting

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