Chapter 8

Economic analysis comparing induction of labour and expectant management for intrauterine growth restriction at term (DIGITAT trial)

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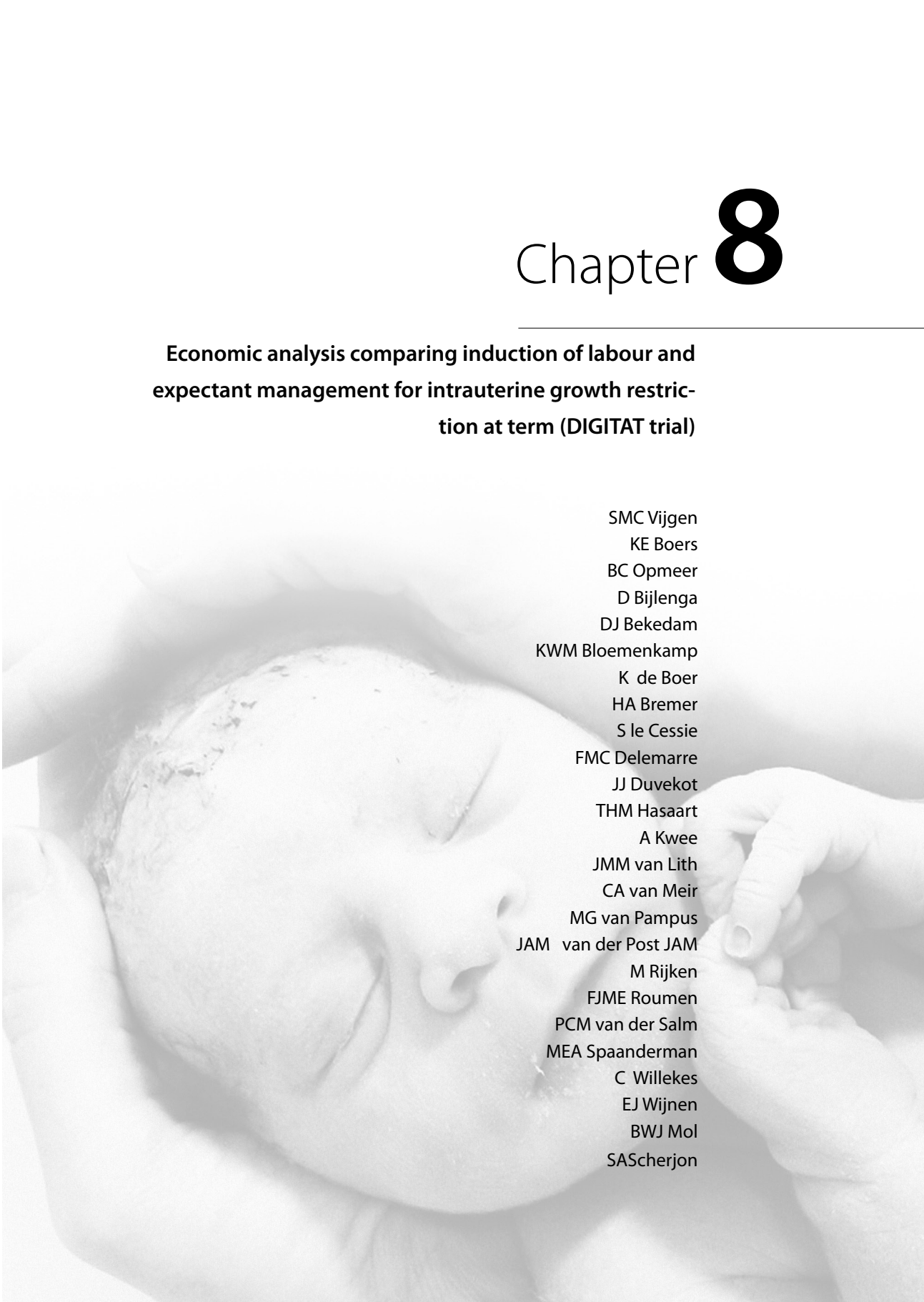

Abstract

Objective: Pregnancies complicated by intrauterine growth restriction (IUGR) are at increased risk for neonatal morbidity and mortality. The Dutch nationwide disproportionate intrauterine growth intervention trial at term (DIGITAT trial) showed that induction of labour and expectant monitoring were comparable with respect to composite adverse neonatal outcome and operative delivery. In this study we compare the costs of both strategies.

Study design: A cost analysis was performed alongside the DIGITAT trial, which was a randomised controlled trial in which 650 women with a singleton pregnancy with suspected IUGR beyond 36 weeks of pregnancy were allocated to induction or expectant management. Resource utilization was documented by specific items in the Case Report Forms. Unit costs for clinical resources were calculated from the financial reports of participating hospitals. For primary care costs Dutch standardized prices were used. All costs are presented in Euros converted to the year 2009.

Results: ante partum expectant monitoring generated more costs, mainly due to longer ante partum maternal stays in hospital. For the durante partu and postpartum stage, induction generated more direct medical costs, due to longer stay in the labour room and longer duration of neonatal high care/medium care admissions. From a health care perspective, both strategies generated comparable costs: on average € 7,106 per patient for the induction group (N=321) and € 6,995 for the expectant management group (N=329) with a cost difference of € 111 (95%CI: - € 1,296 to € 1,641).

Conclusion: In women with pregnancies complicated by IUGR at term, induction of labour generates identical health care costs as compared to expectant management.

Introduction

Intrauterine growth restriction (IUGR) at term is a major problem for obstetricians in clinical practice, because it is associated with increased neonatal mortality and short and long term neonatal morbidity.[1-5] At present there is no consensus among obstetricians on what policy to follow in pregnancies with suspected fetal growth restriction at term. Induction of labour might increase the risk of instrumental deliveries and caesarean sections, and therefore increase maternal and neonatal morbidity as well as costs. Expectant management on the other hand might increase the risk of perinatal complications, including stillbirth.
Since evidence on this point was lacking, we recently performed a randomised clinical trial on the subject, named the Disproportionate Intrauterine Growth Intervention Trial at Term (DIGITAT, number ISRCTN10363217).[6] In this 650 patient study, the composite adverse neonatal outcomes and caesarean sections were comparable in both groups.[7]

In the expected group babies were delivered on average 10 days later and weighted 130 grams more as compared to the induction group. Overall, in women with suspected IUGR at term no important differences were found between induction of labour and expectant monitoring concerning immediate adverse neonatal outcome or operative delivery rate. However, significantly more neonates from the induction group were admitted to high or medium levels of care.[7] It is unclear whether these strategies differ in terms of costs generated by health care utilisation. At present, evidence on costs and cost-effectiveness of management of women with suspected IUGR at term is limited.

This study reports the economic evaluation that we performed alongside the DIGITAT trial, in which induction of labour and expectant monitoring were compared in pregnancies complicated by suspected intrauterine growth restriction beyond 36 weeks of gestation.

Methods

Trial design

Full details of the DIGITAT trial were reported previously.[6] The trial was approved by the Institutional Review Board of the University of Leiden and had local approval from Boards of the other participating hospitals. The trial has been registered in the clinical trial register as ISRCTN10363217.

In short, the study was a multicentre randomised controlled clinical trial in obstetric departments of 8 academic and 44 non-academic hospitals in The Netherlands. Women diagnosed with suspected IUGR beyond 36 weeks of pregnancy with a singleton fetus in cephalic presentation were allocated to either induction of labour or expectant monitoring. Suspected IUGR was defined as a fetal abdominal circumference (FAC) below the 10th percentile, or an estimated fetal weight (EFW) below the 10th percentile, or a flattening of the FAC curve by ultrasound.

In the induction group, labour was induced within 48 hours after randomization, according to local protocol. In the expectant group, patients were monitored by local protocol until the onset of spontaneous delivery with daily fetal movement counts, and at least twice weekly heart rate tracings and weekly ultrasound examination. If there were signs of sub-optimality in any of these recordings induction of labour was the treatment of choice. Maternal monitoring consisted of frequent blood pressure measurements, assessment of proteïnuria and laboratory tests of liver and kidney function and full blood count all at the discretion of the attending obstetricians. Monitoring could take place in an outpatient setting or during admission to the hospital.

All patients who declined randomisation, but who gave authorization for the use of their medical data were registered as non-participants. Identical data were collected prospectively and entered into the trial database. The primary outcome in this trial was a composite measure of adverse neonatal outcome, defined as death before hospital discharge, 5-minute Apgar score < 7, umbilical artery pH < 7.05, or admission to the neonatal intensive care.

Analysis of the clinical endpoints showed comparable neonatal outcomes between both groups, the prevalence of composite adverse neonatal outcome was 17 (5.3%) for the induction group versus 20 (6.1%) in the expectant monitoring group; difference – 0.8% (95% CI – 4,3% to 3.2%). There was no perinatal mortality in the trial. The number of caesarean sections (respectively 45 (14,0%) versus 45 (13.7%); difference 0.3% (95% CI -5.0% to 5.6%)) were comparable as well.[7]

Economic evaluation

A cost analysis was performed alongside the trial. We used a health care perspective, in which only medical costs are included, with a time horizon until hospital discharge. Thereby, by documenting details on utilisation of health care resources, we provide insight in the clinical origins of costs associated with management of these high-risk pregnancies.

As both strategies were comparable in terms of health outcomes, we performed a cost-minimization analysis in which only the costs of both strategies were compared.[8] We differentiated three phases of the clinical process in which costs arise: ante partum costs (from the moment of randomisation until childbirth), costs related to the delivery, and postpartum costs (from the moment of childbirth until hospital discharge). No discounting was applied because all costs occurred within one year.

Resource utilisation

Resource use during the admission period was documented in the Case Report Form (CRF). The following resource items were collected: maternal and neonatal admissions, method of delivery, outpatient visits, medication, maternal laboratory tests, cardiotocograms (CTGs) and fetal ultrasounds. Maternal admissions were differentiated into three levels of care (intensive, medium, or ward). Neonatal admissions were divided into four levels of care (intensive, high, medium, or ward). Neonatal admissions on maternal ward were not included in our analyses because we assumed these were already included in the maternal ward costs.

As induction of labour takes place inside the labour room, we expected that stays

in the labour room will be longer in the induction group due to time needed for induction. This difference was accounted for by measuring use of the labour room as hours between admission to labour room and birth plus one hour extra for extended recovery care, and estimated unit costs associated with one hour of labour room use. In case a caesarean section was performed, use of the operation room (in hours) was estimated as well.

Unit costs

Unit cost estimates were based on several sources: top-down calculations provided by the financial departments in one participating academic and one participating general hospital (for maternal and neonatal admissions to ward, medical care, obstetric high care, (N)ICU and neonatal monitoring), bottom-up calculation (one hour use of the labour room and operating theatre), Dutch standardized prices (visits to primary and paramedical health care providers and outpatient visits), and market prices (medication).[9-10] In Table 1 unit costs together with valuation methods and sources are presented. All unit costs were expressed in 2009 Euros using the consumer pricing index.[11]

Analyses

Group differences in resource use were tested by using the nonparametric Mann-Whitney U test, because such data are generally not normally distributed. Resource use per patient was multiplied by unit costs, and total costs per patient were estimated. Mean total costs per patient as well as median costs were estimated, and differences in total costs between study groups are tested using the nonparametric Mann-Whitney test. Differences in mean costs and 95% confidence intervals were determined by bootstrapping. Statistical and simulation analyses were performed using SPSS software (version 16.0) and Microsoft Excel.

Table 1
Cost-analyses: units of resource use, unit costs, valuation method and volume source

	Unit	Unit cost	Valuation method (source)	Volume source
Medical costs				
*Admission mother**				
hospital stay - ward	Day	359	top-down calculation	CRF
hospital stay - medium care	Day	546	top-down calculation	CRF
hospital-stay - intensive care	Day	1742	top-down calculation	CRF
*Admission child**				
hospital stay - medium care	Day	546	top-down calculation	CRF
hospital stay - high care	Day	1462	top-down calculation	CRF
hospital-stay - NICU	Day	1514	top-down calculation	CRF
specialist care	Hour	72	Dutch costing guidelines	CRF/AQ
outpatient visit*	Visit	85	top-down calculation	CRF/AQ
psychologist	Hour	35	Dutch costing guidelines	AQ
midwife	Hour	35	Dutch costing guidelines	AQ
general practitioner	Visit	22	Dutch costing guidelines	AQ
paramedical	Visit	25	Dutch costing guidelines	AQ
home care	Hour	33	Dutch costing guidelines	AQ
Induction methods#	Gift	16	Pharmacotherapeutic website	CRF
Medication#	dose per day	7	Pharmacotherapeutic website	CRF
Analgesics during labour#	procedure	167	top-down calculation	CRF
Neonatal monitoring#	procedure	93	top-down calculation	CRF
Operation room*	Hour	145	bottom-up calculation	CRF
Labour room*	Hour	85	bottom-up calculation	CRF
Non-medical costs				
Travel costs- car	Km	0.18	Dutch costing guidelines	AQ
Travel costs- public transport	km	0.18	Dutch costing guidelines	AQ
Informal care	Hour	9.10	Dutch costing guidelines	AQ
Productivity loss	Hour	27	Dutch costing guidelines	AQ

* the mean of the unit cost for an academic hospital and for a general hospital is presented
CRF= Case Report Form
AQ= additional questionaire
# the mean of several methods/medications is presented

Results

Between November 2004 and November 2008, we approached 1.116 women, of whom 650 were randomised to induction (n = 321) or expectant management (n = 329), 452 declined randomisation and 14 refused any use of identifiable data.

Average volumes of resource utilization, total costs in each study group as well as average costs per patient are presented in Table 2. During the ante partum phase from moment of randomisation until start of delivery, maternal admissions were compared to the induction group longer in the expectant monitoring group, respectievely 2.8 versus 8.2 days for medium care (p=< 0.05) and 2.2 versus 4.7 days on maternal ward (p<0.001). More outpatient CTGs (2.1 versus 4.8, p<0.001), more ultrasounds (1,3 versus 2,1, p<0.001), more scheduled outpatient visits (1.9 versus 4.4, p<0.001), more unscheduled outpatient visits (1.3 versus 1.6, p<0.001) and more maternal assessments (5.4 versus 9.9, p<0.001) occurred in the expectant monitoring group. Admission because of labour was somewhat longer in the induction group (1.8 days versus 1.4 days, p<0.001).
The duration of admission in the labour room and/ or operating theatre was also longer for the induced patients in case of spontaneous delivery (15.4 versus 8.3 hours, p<0.001), in case of vacuum or forcipal extractions (25 versus 11 hours, p<0.05) and in caesarean deliveries (18.3 versus 11.9 hours, p<0.05). From childbirth until hospital discharge no significant differences appeared in the duration of maternal and neonatal admissions. However, as can be seen from table 2 more neonates in the induction group were admitted to medium care wards compared to the expectant monitoring group (44% versus 31%).

Table 2
:Resource use, mean costs per patient and total costs, randomised patients (2009 Euros)

		Induction (N=321)				Expectant management (N=329)				
	Unit	% patients using care	Mean volume*	Total Costs	Mean Costs pp	% patients using care	Mean volume*	Total Costs	Mean Costs pp	Difference (I-EM)
Maternal admission MC	days	3%	2.8	12198	38	4%	8.2	40138	122	-84
Maternal admission ward	days	24%	2.2	54891	171	33%	4.7	162526	494	-323
Home care	days	3%	6.5	2247	7	8%	8.7	7238	22	-15
Outpatient CTGs	procedure	20%	2.1	4173	13	72%	4.8	34216	104	-91
CTGs during admission	procedure	98%	4.6	43335	135	97%	7.0	66787	203	-68
Ultrasounds	procedure	12%	1.3	1284	4	66%	2.1	13818	42	-38
Scheduled outpatient visits	visit	21%	1.9	10593	33	72%	4.4	89817	273	-240
Unscheduled outpatiet visits	visit	4%	1.3	1284	4	26%	1.6	11515	35	-31
Maternal assessments	procedure	83%	5.4	11556	36	97%	9.9	25004	76	-40
Medication#				32,1	0,1			329	1	-0,9
Laboratorium tests	test	67%	1.6	642	2	61%	1.7	658	2	0
Total ante partum				142235,1	443			452046	1374	-931
Admission because of labour	day	90%	1.8	175587	547	86%	1.4	136864	416	131
Induction PGE gel	Gift	52%	1.9	13482	42	20%	1.8	4935	15	27
Induction PGE tablets	Gift	8%	3.0	288,9	0,9	7%	2.1	197,4	0,6	0,3
Amniotomy and oxytocin	procedure	24%	-	64,2	0,2	18%	-	65,8	0,2	0
Medication during labour#	Unit	51%	-	24396	76	42%	-	21056	64	12
Spontaneous route of delivery	hours	78%	15.4	322605	1005	78%	8.3	179963	547	458
Instrumentel delivery	hours	8%	25.0	57138	178	8%	11.1	25662	78	100
Caesarean delivery	hours	14%	18.3	71904	224	14%	11.9	47376	144	80
Episiotomy	procedure	21%	-	1284	4	28%	-	1645	5	-1
Total delivery				666749,1	2077			417764	1270	807
Maternal admission IC	days	1%	6.0	0	49	1%	5.0	13160	40	9
Maternal admission MC	days	1%	3.5	5457	17	2%	4.1	12502	38	-21
Maternal admission ward	days	63%	4.1	277665	865	63%	3.9	272083	827	38
Maternal homecare	days	9%	4.3	4173	13	10%	3.7	3948	12	1
Neonatal admission IC	days	3%	6.4	88275	275	4%	13.1	257936	784	-509
Neonatal admission HC	days	8%	14.5	511674	1594	8%	11.0	426055	1295	299
Neonatal admission MC	days	44%	8.5	549552	1712	31%	9.5	423752	1288	424
Consult paediatrician	visit	71%	1.1	17976	56	65%	1.1	17108	52	4
Neonatal monitoring	procedure	7%	-	1605	5	10%	-	4935	15	-10
Total postpartum				1456377	4586			1418319	4351	235
Total costs					7106				6995	111

* of patients using care # medication costs are an summation of several medications, therefore no unit and mean volume is given

A summary of the mean and median costs per patient is provided in Table 3. In the ante partum period mean costs per patient appeared to be higher in the expectant monitoring group (difference - €931). On the other hand, during delivery induction of labour generated more costs than expectant management (difference €807), mainly because induction required a longer stay labour room and/ or operating theatre.

In the postpartum period, women in the induction group also generated more costs than women monitored expectantly (difference: €235).

Overall, mean costs per patient were €7.106 for induction and €6.995 in the expectant monitoring group (difference €111: 95% CI -1295 to 1640).

Table 3
Comparison of costs between randomised induction of labour and expectant management

	Induction (N=321)	**Expectant management (N=329)**	**Differential mean cost***		
	Mean	Median (IQR)	Mean	Median (IQR)	(95% CI)#
Total ante partum	443	218 (110-573)	1374	824 (485-1694)	
-931					
Total delivery	2077	1399 (916-2785)	1270	949 (635-1478)	807
Total postpartum	4586	1941 (596-5136)	4351	1264 (138-4271)	235
Total costs	7106	4680 (2296-8610)	6995	3954 (2164-7569)	111(-1296- 1641)

*Induction minus expectant management
non-parametric confidence interval based on 1000 bootstrap replications

Discussion

In this study we estimated the costs of pregnant women with a diagnosis of IUGR at term in whom labour was induced and those who were monitored expectantly using the data of the DIGITAT trial. The trial did not detect differences in maternal or neonatal outcomes or in operative delivery rates, so the economic evaluation was set up as a cost-minimization analysis. We found comparable costs after induction of labour and expectant management in women with suspected intrauterine growth restriction at term. Within a study horizon from moment of randomisation until postpartum hospital discharge induction of labour and expectant management resulted in comparable medical costs per patient. Unsurprisingly, the distribution of costs over the different phases in each strategy shows higher ante partum costs (due to longer maternal admissions) in the expectant group and higher delivery costs (due to the induction itself) in the induction group. Costs due to postpartum maternal and neonatal admissions are comparable between both groups.

This adds to equivalent fetal and maternal outcomes as well as quality of life[12], indicating that both approaches are both acceptable management strategies. If a policy of induction for near term growth restriction is to be followed, deferring induction until 38 weeks, while strictly monitoring mother and child, may prevent complications of late prematurity and neonatal admissions.[13] However, beyond 38 weeks, there is not much to win by further postponing delivery, neither in medical outcomes, and probably nor in costs.

To our knowledge this is the first economic evaluation that prospectively compared these strategies in this patient population. We used trial-based data that were collected prospectively.

In earlier studies we reported comparable neonatal and maternal outcomes after labour induction and expectant management in at term IUGR.[7] The same applies to more detailed neonatal morbidity.[13] A quality of life study alongside the DIGI-

TAT trial was performed by Bijlenga et al. on behalf of the DIGITAT study group. In this study health related quality of life was measured in 361 randomised women, 6 weeks and 6 months after childbirth using validated questionnaires. From the results it could be concluded that in pregnancies complicated by IUGR beyond 36 weeks, induction of labour does not affect the long-term maternal quality of life. [12]
The equipoise in antenatal and postnatal costs in the DIGITAT trial was not found in the cost-analysis of a comparable RCT, that compared induction to expectant management in women with gestational hypertension or mild pre-eclampsia at term.[14-15] In this study induction of labour was less costly than expectant monitoring because of differences in resource use in the ante partum period.[15]
Because more than 50 hospitals from all over the Netherlands, teaching as well as non-teaching, participated to the DIGITAT trial the study population was representative for Dutch population. However, women who declined randomisation were older, slimmer, higher educated and smoked less.7,[16] In a comparison between participants and non-participants, we found a trend towards worse neonatal outcomes and higher operative delivery rates among non-participants. Probably this finding would translate into higher costs in this group, even though they had higher SES.[16]

Our analysis focused on short term and a with a health care perspective. The advantage of that is the use of direct clinical trial data for both costs and effects.

We also tried to study longer term and societal costs as well by analyzing questionnaires filled out by a very small subsample of the study population (n=27). After including these costs, induction of labour became significantly more expensive than expectant monitoring. However, because of the unreliability of the follow-up data in this economic analysis we decided to focus on the short-term medical costs. Because growth restriction is associated with a less favourable (neuro)developmental outcome, we also investigated the outcome of children randomised during DIGITAT after two years.[17] As that follow-up indicated no differences in child behaviour at 2 years between induction and expectant management, we think it is not necessary

to include long term and societal costs for the children in our economic analysis. Strengths of our study are the use of trial-based data for the economic analysis, and exactly the same patients were studied as for the clinical analysis. Transferring the data to the general patient population is valid because of the large number and diversity of the participating hospitals.

With this study we further aimed to define the best strategy in at term IUGR by analysing costs generated by induction compared to expectant management, since primary neonatal and delivery outcomes, as well as more detailed neonatal morbidity and maternal quality of life were comparable between the two strategies. The antenatal costs of expectant management in IUGR were higher due to higher consumption of medical care by monitoring mother and child. However, induction group babies had a higher medical consumption after birth, mainly due to neonatal hospital admissions in exchange. In order to do defer delivery in IUGR, both mother and child were strictly monitored, until either labour was induced because of fetal or maternal deterioration or spontaneous delivery started. As expected, this imposed higher resource use antenatal. On the contrary, more children were admitted to intermediate levels of care after induction, mainly due to lower gestational age and related birth weight at delivery[12], accounting for higher resource use after birth. Since costs are not higher after expectant management, postponing delivery beyond 38 weeks gestation for as long as neonatal condition is reassuring is reasonable, providing monitoring of mother and child. By this means, the number of neonatal admissions can be restricted. We plan to analyse whether this approach will generate less costs.

Induction of labour and expectant monitoring in at term IUGR have comparable outcomes immediately after birth in terms of obstetrical outcomes, maternal quality of life and costs. Providing strict monitoring of mother and child induction of labour is reasonable to pre-empt possible stillbirth in suspected IUGR, if feasible after 38 weeks gestation.

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