Induction of labour versus expectant management for prelabour rupture of the membranes at term: an economic evaluation

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Abstract

Background: As the interval between rupture of the fetal membranes at term and delivery increases, so may the risk of fetal and maternal infection. Recently the TERMPROM (Term Prelabor Rupture of the Membranes) Study Group reported the results of a randomized controlled trial comparing 4 management strategies: induction with oxytocin (IwO), induction with prostaglandin (IwP), and expectant management and induction with either oxytocin (EM-O) or prostaglandin (EM-P) if complications developed. The study found no statistically significant differences in neonatal infection and cesarean section rates between any of the 4 groups.

Objective: To conduct an economic evaluation comparing the cost of (a) IwO and EM-O, (b) IwP and EM-P and (c) IwO and IwP.

Design: An economic analysis, conducted alongside the clinical trial, using a third-party payer perspective. Analysis included all treatment costs incurred for both the mother and the baby. Information on health care utilization and outcomes was collected for all study participants. Three countries (Canada, the United Kingdom and Australia), corresponding to the largest study recruitment, were chosen for calculation of unit costs. For each country, the base, low and high estimates of unit cost for each service item were generated. Intention-to-treat analysis. Extensive statistical and sensitivity analyses were performed.

Results: The median cost of IwO per patient was significantly lower statistically than that of EM-O and IwP. This result held in all 3 countries compared (–$114 and –$46 in Canada, –£113 and –£63 in the UK, and –A$30 and –A$49 in Australia) and after an extensive sensitivity analysis. There was no statistically significant difference in median cost per patient between IwP and EM-P.

Conclusion: Although the clinical results of the TERMPROM study did not find IwO to be preferable to the other treatment alternatives, the economic evaluation found it to be less costly. However, these cost differences, even though statistically significant, are not likely to be important in many countries. When this is the case, the authors recommend that women be offered a choice between management strategies.

Résumé

Contexte : Le risque d'infection chez le foetus et la mère augmente proportionnellement à l'intervalle entre la perte des eaux à terme et l'accouchement. Le Groupe d'étude sur la perte des eaux à terme avant le travail (*Term Prelabor Rupture of the Membranes* ou TERMPROM) a présenté récemment les résultats d'une étude contrôlée randomisée dans le cadre de laquelle on a comparé 4

Evidence

Études

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See reference 7 for a complete list of participants in the TERMPROM Study Group.

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stratégies de traitement : induction à l'oxytocine (IO), induction à la prostaglandine (IP) et traitement expectant et induction, en cas de complication, à l'oxytocine (TE-IO) ou à la prostaglandine (TE-IP). On n'a constaté aucune différence statistiquement significative entre les 4 groupes.

Objectif : Effectuer une évaluation économique pour comparer le coût de : a) l'IO et le TE-IO, b) l'IP et le TE-IP et c) l'IO et l'IP.

Conception : Analyse économique, effectuée parallèlement à l'étude randomisée, dans l'optique du tiers payeur. L'analyse a tenu compte de tous les coûts de traitement engagés à la fois pour la mère et le bébé. On a recueilli des renseignements sur l'utilisation des soins de santé et les résultats dans le cas de toutes les participantes. Trois pays (Canada, Royaume-Uni et Australie) correspondant à l'effectif des sujets d'étude le plus important, ont été choisis aux fins du calcul des coûts unitaires. On a produit, pour chaque pays, les estimations de base, faibles et élevées des coûts unitaires de chaque service. Analyse en fonction de l'intention de traiter. On a effectué des analyses statistiques détaillées et des analyses de sensibilité.

Résultats : Le coût médian de l'IO par patiente a été significativement moins élevé sur le plan statistique que celui du TE-IO et de l'IP. Cette constatation est évidente dans les 3 pays à l'étude (–114 $ et –46 $ au Canada, –113 £ et –63 £ au R.-U. et –30 $A et –39 $A en Australie) et après l'analyse détaillée de sensibilité. La différence du coût médian par patiente entre les interventions IP et TE-IP n'était pas significative sur le plan statistique.

Conclusion : Même si les résultats cliniques de l'étude TERMPROM n'ont pas indiqué que l'IO soit préférable aux autres stratégies de traitement, l'évaluation économique a révélé qu'elle était moins coûteuse. Cependant, même si ces différences de coûts sont significatives sur le plan statistique, elles ne seront pas susceptibles d'être importantes dans beaucoup de pays. Lorsque c'est le cas, les auteurs recommandent que l'on offre aux femmes un choix de stratégies de traitement.

When a pregnancy reaches term, women normally expect labour to begin spontaneously, without medical or surgical assistance. However, for approximately 8% of women the membranes rupture but labour does not begin spontaneously within the next few hours. Because the risk of maternal and fetal infection is known to increase with increasing duration between membrane rupture and delivery, artificial labour induction may be preferable for these women and their babies.[1,2] Others believe that waiting for labour to begin spontaneously is preferable if there is no evidence of fetal or maternal compromise, because the risk of cesarean section may be lower.[3,4] Because of the limited information available it was difficult to determine which approach is better, and thus a clinical trial was called for.[5,6].

The Term Prelabor Rupture of the Membranes (TERMPROM) Study, a large, multicentre, international randomized controlled trial involving 5041 women, was conducted.[7] The participants were randomly assigned to 1 of 4 management strategies: induction with oxytocin (IwO), induction with prostaglandin (IwP), and expectant management and induction with either oxytocin (EM-O) or prostaglandin (EM-P) if complications developed. The study found no statistically significant differences between any of the 4 groups in neonatal infection rates, which varied from 2.0% to 3.0%, or cesarean section rates, which varied from 9.6% to 10.9%. The investigators did find a significantly lower rate of maternal infection in the IwO group than in the EM-O group, but the rate did not differ significantly between the IwP and EM-P groups or between the 2 induction groups. They also found that the time from randomization to delivery for women in the IwO group was significantly less than that for women in the other groups and that women in the induction groups were more likely to view their care positively than women in the EM groups. Hence, on the basis of secondary outcomes the TERMPROM Study Group concluded that the results could be interpreted as favouring the clinical policy of induction of labour with oxytocin.

In an editorial accompanying the TERMPROM report Duff[8] compared the study findings with those from previous research. One of his criticisms of the TERMPROM study was that the investigators "did not examine the relative costs of the alternative plans of management." His prediction was that costs would be higher for expectant management, and he used this as one of the reasons to support his recommendation to abandon the practice of expectant management. It was not mentioned in the

initial report that a prospective economic evaluation was conducted alongside the clinical portion of the TERMPROM Study. In this article, we report the estimated cost of each management strategy and discuss the economic and policy implications of our findings.

Methods

Clinical trial

The TERMPROM Study was a large, multicentre randomized controlled trial involving 72 hospitals in Canada, the UK, Australia, Israel, Sweden and Denmark. A detailed description of the trial was given in the initial report.[7] In brief, we studied women with prelabour rupture of the membranes at term. Women were screened for eligibility (ruptured membranes, gestational age of at least 37 weeks and a single fetus in cephalic presentation) and randomly assigned to 1 of the 4 management strategies. Women were excluded if they were in active labour, a previous attempt at induction had failed or there was a contraindication to induction or expectant management. The study was approved by the research-ethics committees at all the participating centres, and women gave informed consent before being enrolled in the study. In total, 5041 women participated. The primary outcome measure was neonatal infection, and the secondary outcome measures were rates of cesarean section and the women's evaluation of their treatment.

For women assigned to the 2 induction groups, labour was induced as soon as possible after randomization with either oxytocin (infused at a rate titrated to the women's contractions) or prostaglandin E_2 gel (1 or 2 mg). Women assigned to the 2 EM groups were either admitted to the hospital or managed on an outpatient basis. They waited for labour to begin spontaneously unless there was evidence of fetal or maternal compromise, or until 4 days had elapsed, at which time labour was induced with either oxytocin or prostaglandin E_2 gel. Monitoring of women in the EM groups included measurement of temperature twice daily, reporting of fever or changes in the colour or odour of amniotic fluid and, for some women, additional monitoring tests.

Economic analysis

An economic analysis was conducted alongside the clinical trial. Our economic hypothesis when designing the trial was that induction with oxytocin would be both more effective *and* less expensive when compared with the other 3 strategies. We were aware of the methodological issues that arise in undertaking economic analysis alongside clinical trials[9,10] and acted accordingly. A third-party-payer perspective was chosen for the cost analysis. Accordingly, all hospital expenses (e.g., for nursing services, operative procedures and diagnostic services), professional fees and the cost of induction medications were included. Indirect costs such as patient expenses and time off work were excluded. The analysis included all treatment costs incurred for both the mother and baby from the time of randomization to hospital discharge. Costs were calculated for the year 1995.

Health care utilization

Information on health care utilization and outcomes was collected for all study participants. We anticipated that the direct medical cost of treatment would depend on a number of factors: hospital length of stay; length of stay of baby in neonatal intensive care unit (NICU); operative procedures (cesarean section); maternal and neonatal infection rates; length of oxytocin induction; number of prostaglandin gel applications; diagnostic tests and procedures; and type of hospital (teaching v. community). Accordingly, the case report forms used in the study were designed to collect this level of information for the cost analysis.

For the purpose of this analysis, the time in the antenatal ward was calculated as the time from hospital admission to the start of active labour unless women had labour induced with oxytocin, in which case it was the time from hospital admission to the start of labour induction. If women had labour induced with prostaglandin gel, an additional hour per application of gel was added to their time in the antenatal ward to account for the additional time required by nurses to monitor the fetus following gel application. The time in the labour and delivery ward was calculated as the time from the onset of active labour to delivery unless women had labour induced with oxytocin, in which case it was the time from the start of labour induction to delivery. For women who began labour at home and were later admitted to hospital, the time in the labour and delivery ward was calculated as the time from hospital admission to delivery. If a patient received epidural anesthesia the duration of the epidural was calculated as being equal to the time in the labour and delivery ward. The time in the postpartum ward was calculated as the time from delivery to discharge for every patient. The tests specifically required as part of the protocol but not considered standard practice (e.g., first blood culture for all infants) were not included. Finally, the category of operative vaginal delivery included low-forceps, mid-forceps and vacuum extraction deliveries.

Unit costs

Although the use of health care resources was recorded

at the time of the original study, their associated unit costs were collected toward the end of the trial. Reliable unit costs for health care services were not readily available in any of the 6 participating countries, and thus they had to be calculated using financial and statistical reports from each hospital. It is well known that the costs of different interventions are system dependent.[11] Because it would have been prohibitively expensive to calculate unit costs in all 72 hospitals, selected centres and countries were chosen for calculation of unit costs. Three countries (Canada, the UK and Australia), corresponding to the largest study recruitment, were chosen. Within each country, hospitals were chosen on the basis of their recruitment rate, the quality and accessibility of their financial and statistical information, and the type and size of the hospital. In total, 12 hospitals were chosen: 6 (3 community and 3 teaching) from Canada, 4 (2 community and 2 teaching) from the UK, and 2 (1 community and 1 teaching) from Australia. All of these hospitals were visited, and the relevant information was collected and validated.

Unit costs were applied to utilization data of individual patient services. Because unit cost estimates varied across the 12 hospitals, cost calculations from each hospital were used to provide base, low and high unit cost estimates for each service item within each country. Base estimates for a given country were calculated as the mid-point between the low and high unit costs for the service from all the hospitals chosen in that country. Low and high estimates for a given country represented the lowest and highest unit costs estimated for the service from all the hospitals chosen in that country. Because of fee-for-service reimbursement in Canada, professional fees were obtained from the provinces where the chosen hospitals were located.[12–14]

We could not obtain cost-per-hour estimates for the time in the antenatal and labour and delivery wards. Instead, cost estimates were obtained by type of delivery (i.e., vaginal, operative vaginal or cesarean section). These estimates were based on the hospital-specific use of labour, materials and supplies, and the length of time in labour and delivery for each type of delivery. Because these cost estimates did not take into account the time differences in the antenatal ward between the 4 management strategies, an additional amount for nursing costs was added based on hourly nursing wages, the nurse-to-patient ratio (which varied from 1:3 to 1:7) and the time in the antenatal ward. For those who received oxytocin induction a cost reflecting the 1:1 nurse-to-patient ratio was added to the length of time from the start of oxytocin induction to active labour.

Statistical and sensitivity analyses

All results were analysed according to the intention-to-treat model. Cost analyses by treatment group were compared by means of the Wilcoxon rank-sum test.[15] Statistical tests were done for 3 comparisons: (a) IwO versus EM-O, (b) IwP versus EM-P and (c) IwO versus IwP. A p value of less than 0.05 was considered to indicate statistical significance for differences in costs between the groups.

The above analysis captures only differences in resource utilization patterns[16] and thus calls for the use of sensitivity analysis to explore the robustness of the results over a range of alternative values of unit costs. To generate a set of alternative unit cost values based on reality we decided to collect costs at a number of hospitals as described earlier. In total, we used 9 sets of unit costs in the analysis (i.e., 3 countries, and for each country 3 sets of unit costs [base, low and high]). We repeated the statistical analysis 9 times to check whether the results were sensitive to the set of unit costs chosen.

Results

In Table 1 we describe the key health care services variables that were collected for the economic analysis. With respect to high-cost services, infants in the IwO group were less likely to be admitted to an NICU or special care nursery than those in the EM-O group (12.08% v. 18.13%, $p < 0.001$). As well, infants in the IwO group spent significantly less time in a special care nursery than those in the EM-O group, but not significantly less time in an NICU. The length of stay in the antenatal ward was significantly shorter statistically in the IwO group than in the EM-O group (3.50 v. 8.33 hours, $p < 0.001$) or the IwP group (3.50 v. 11.17 hours, $p < 0.001$). The length of stay in the antenatal ward was significantly shorter statistically in the EM-P group than in the IwP group (8.92 v. 11.17 hours, $p < 0.001$).

Table 2 presents the base, low and high unit cost estimates for selected health care resources for Canada, the UK and Australia. The unit costs are presented in each country's currency in 1995 figures. The "relative prices" (unit costs) were not similar across the countries. For example, the cost of cesarean section compared with that of vaginal delivery was 1.45 times more expensive in Canada, 4.35 times more expensive in the UK and 1.44 times more expensive in Australia. The larger difference in the UK reflects, among other things, the use of different resources (e.g., midwives performing vaginal deliveries v. specialists performing cesarean sections) to perform these procedures. The variability in unit cost within a country (reflected in the low and high estimates) was substantial for the high-cost services.

The median costs per patient in the 4 management groups and the cost differences between the IwO and

EM-O groups, the IwP and EM-P groups and the IwO and IwP groups, and their statistical significance, are presented in Table 3. The overall distributions of the cost results were highly skewed in each group. One of the main factors for this was the high cost of NICU and special nursery care. We found that IwO was significantly less expensive statistically than both EM-O and IwP for all 9 sets of unit costs used. We did not find statistically significant differences between the costs of IwP and EM-P. Although the differences in costs in the last 2 columns in Table 3 are similar in magnitude, the differences in statistical significance are due to differences in variance.

Discussion

We found that the difference in cost between IwO and the other management options was statistically significant, but is it economically important? For example, the cost differences between IwO and EM-O (according to the base unit cost estimate from the 3 countries) as a percentage of the median cost per patient treated with EM-O were 3.6% (Canada), 9.2% (UK) and 1.4% (Australia). In other words, the saving per case was small in Australia and maybe Canada, but not in the UK. However, a small saving per case can still be meaningful at an institutional or national level. For example, the annual savings to the Canadian health care system by changing from EM-O to IwO would be almost $3.5 million (about 0.005% of the total annual health care expenditures). This example also illustrates the sensitivity of the analysis to variations in local (i.e., country in our example) unit costs and the need to collect unit costs in more than 1 centre.

In the clinical portion of the study, blood samples were taken from all babies, for culture and complete blood count, within 24 hours after delivery and before treatment with antibiotics. This was not usual care. As we mentioned earlier, the literature on methods for economic evaluation recommends that these types of services "induced" by the study protocol be excluded, and so they were. An important question is whether to include services that result from having these nonroutine tests done in a clinical trial setting. In our study we did not keep the fact that these tests were done and their results from the caregivers. Thus, the results could have influenced prac-

Table 1: Health care utilization, by management strategy

Item*	Induction with oxytocin (IwO) *n=1258*	Induction with prostaglandin (IwP) *n=1259*	Expectant management with oxytocin (EM-O) *n=1263*	Expectant management with prostaglandin (EM-P) *n=1261*
Outpatient visits, mean no. (range)	0.01 (0–2)†‡	0.06 (0–3)‡§	0.17 (0–5)†	0.16 (0–5)§
Ultrasound of AFV, mean no. (range)	0.05 (0–3)†	0.04 (0–3)§	0.09 (0–4)†	0.09 (0–6)§
LOS in antenatal ward, median hours (5th and 95th percentiles)	3.50 (0.65, 16.75)†‡	11.17 (2.33, 30.67)‡§	8.33 (0, 57.88)†	8.92 (0, 62.42)§
Time from oxytocin induction to labour, median hours (5th and 95th percentiles)	2.33 (0, 9.92)†‡	0 (0, 2.50)‡	0 (0, 5.75)†	0 (0, 2.50)
Induction with oxytocin, no. (%) of women	1115 (88.63)	130 (10.33)	264 (20.90)	106 (8.41)
Labour augmented with oxytocin, no. (%) of women	41 (3.26)	413 (32.80)	366 (28.98)	446 (35.37)
Induction with prostaglandin gel, no. (%) of women	8 (0.64)	1112 (88.32)	31 (2.45)	199 (15.78)
Prostaglandin gel applications, mean no. (range)	0.01 (0–1)†‡	1.23 (0–4)‡§	0.03 (0–3)†	0.22 (0–4)§
Type of delivery, no. (%) of women				
Spontaneous vaginal	898 (71.38)	910 (72.28)	884 (69.99)	897 (71.13)
Operative vaginal	233 (18.52)	228 (18.11)	256 (20.27)	226 (17.92)
Cesarean section	127 (10.10)	121 (9.61)	123 (9.74)	138 (10.94)
Infants seen in NICU or SCN, no. (%)	152 (12.08)†	178 (14.14)	229 (18.13)†	207 (16.42)
LOS, median hours (5th and 95th percentiles)				
In NICU	0 (0, 3.75)	0 (0, 14.00)	0 (0, 16.75)	0 (0, 31.98)
In SCN	0 (0, 17.82)†	0 (0, 29.50)	0 (0, 40.00)†	0 (0, 28.83)
In postpartum ward	62.97 (22.40, 130.78)	62.50 (20.03, 136.88)	63.02 (23.05, 137.18)	62.97 (23.03, 134.22)

*AVF = amniotic fluid volume, LOS = length of stay, NICU = neonatal intensive care unit, SCN = special care nursery.
†$p < 0.001$ for difference between IwO and EM-O.
‡$p < 0.001$ for difference between IwO and IwP.
§$p < 0.001$ for difference between IwP and EM-P.

tice. Any additional treatments should not normally be counted in an economic analysis because they do not represent usual care. However, if the blood cultures had not been done, problems might have developed that would have necessitated other interventions, but it is hard (if not impossible) to predict what those problems would be. In the absence of a better solution, we felt that including the additional services generated as a result of performing the blood tests was appropriate because the outcomes of the clinical trial might have been influenced by treatments resulting from these additional tests.

In the clinical trial, we left it to the clinicians to decide when to admit women in the EM groups to hospital and when to admit their babies to the NICU. Hence, some babies might have been admitted to the NICU for observation because of hospital policy or popular opinion that they might be at greater risk for infection if managed expectantly. If participating centres had encouraged more women (i.e., more than the 40% in the EM groups in the study) to go home while awaiting spontaneous labour or had admitted fewer babies to NICUs, and if such a reduced use of resources were not to be associated with an increase in rates of adverse outcomes, the cost of expectant management would have been lower. We cannot be certain, however, that such altered approaches to expectant management would have resulted in the same outcomes as those observed in the clinical trial.

Some women may wish to avoid having their labour started artificially or having an intravenous infusion. Should women be offered the choice between the different management options described in our study? In his editorial accompanying the report of the clinical trial, Duff[8] stated that both oxytocin and prostaglandin are effective for inducing labour in women at term. However, he stated that expectant management, followed by delay in induction of labour, "is a practice that should be aban-

Table 2: Estimated base, low and high unit costs of selected health care resources, by country

Resource	Country; base (low, high) unit costs*		
	Canada, Can$	United Kingdom, £	Australia, A$
Outpatient visit	25.65 (17.78, 33.52)	59.00 (38.00, 80.00)	33.50 (24.50, 42.50)
Ultrasound of AFV	125.48 (73.03, 177.93)	50.00 (24.00, 76.00)	98.75 (98.75, 98.75)
Antenatal nursing care, per hour	6.04 (4.73, 7.34)	5.26 (3.33, 7.19)	2.34 (2.07, 2.61)
Oxytocin induction, nursing cost per hour	26.12 (24.94, 27.30)	10.01 (8.58, 11.43)	16.10 (15.68, 16.52)
Oxytocin, 10 units/mL	0.30 (0.30, 0.30)	0.23 (0.21, 0.24)	1.10 (0.89, 1.30)
Prostaglandin gel application, 2 mg	51.70 (51.70, 51.70)	18.51 (18.04, 18.98)	50.39 (49.14, 51.64)
Type of delivery			
Spontaneous vaginal	1472.33 (1038.74, 1905.91)	307.00 (178.00, 436.00)	1257.70 (767.40, 1748.00)
Operative vaginal	1609.42 (1148.97, 2069.86)	545.50 (341.00, 750.00)	1257.70 (767.40, 1748.00)
Cesarean section	2139.44 (1537.78, 2741.10)	1335.72 (661.44, 2010.00)	1802.75 (873.24, 2732.25)
NICU, per hour	48.26 (46.22, 50.29)	28.15 (18.50, 37.80)	44.23 (NA,† 44.23)
SCN, per hour	25.90 (20.07, 31.73)	9.48 (5.58, 13.38)	15.07 (14.81, 15.34)
Postpartum ward, per hour	20.07 (11.39, 28.75)	11.07 (7.19, 14.94)	13.15 (12.50, 13.79)

*Costs are given in the currency of the particular country and are in 1995 figures. Base estimates were calculated as the midpoint of the low and high unit costs for the service for all hospitals chosen in a given country.
†NA = not available.

Table 3: Median cost per patient and cost difference between treatment arms*

Unit cost estimates	Management strategy				Pairwise comparisons (and *p* values)		
	IwO	IwP	EM-O	EM-P	IwO v. EM-O	IwP v. EM-P	IwO v. IwP
Canada, Can$							
Base	3056	3102	3170	3142	–114 (0.004)	–40 (0.9321)	–46 (0.0217)
Low	2025	2056	2077	2070	–52 (0.0152)	–14 (0.4316)	–31 (0.0103)
High	4152	4214	4317	4284	–165 (0.0028)	–70 (0.845)	–62 (0.0346)
United Kingdom, £							
Base	1110	1173	1223	1203	–113 (0.0001)	–30 (0.368)	–63 (0.0004)
Low	705	747	779	759	–74 (0.0001)	–12 (0.6949)	–42 (0.0003)
High	1516	1598	1674	1646	–158 (0.0001)	–48 (0.2554)	–82 (0.0004)
Australia, A$							
Base	2191	2240	2221	2237	–30 (0.0342)	3 (0.4369)	–49 (0.0084)
Low	1630	1671	1654	1666	–24 (0.0439)	5 (0.3524)	–41 (0.01)
High	2751	2802	2789	2797	–38 (0.0262)	5 (0.492)	–51 (0.0064)

doned because it may be associated with an increased frequency of maternal and neonatal infection and increased hospital expenses, and it is less favourably regarded by patients." Our opinion on this question differs from that of Duff. Based on the results of the clinical trial and the economic evaluation, we define the situation as one in which, at least clinically, there is no right or wrong choice. It represents a trade-off between an increased risk of clinical chorioamnionitis and a longer period of waiting for the delivery if an expectant-management strategy is chosen versus an aversion toward labour being induced artificially or the wish to avoid an intravenous infusion. Also, the difference in cost, at least in Canada and Australia, is very small. Hence, the choice becomes one of preference from the perspective of an informed patient. As has been done in other clinical settings,[17–20] it will be important to find out which management strategy is preferred by fully informed women at the point of decision-making. The findings from the clinical portion of the TERMPROM Study that women in the induction groups felt more positively than those in the EM groups about the treatment they received should be qualified by the fact that women in the study (as in any randomized controlled trial) were not presented with a choice.

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