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ORIGINAL ARTICLE

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Elective cesarean section to prevent anal incontinence and brachial plexus injuries associated with macrosomia—a decision analysis

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Abstract Our aim was to determine the cost-effectiveness of a policy of elective C-section for macrosomic infants to prevent maternal anal incontinence, urinary incontinence, and newborn brachial plexus injuries. We used a decision analytic model to compare the standard of care with a policy whereby all primigravid patients in the United States would undergo an ultrasound at 39 weeks gestation, followed by an elective C-section for any fetus estimated at ≥4500 g. The following clinical consequences were considered crucial to the analysis: brachial plexus injury to the newborn; maternal anal and urinary incontinence; emergency hysterectomy; hemorrhage requiring blood transfusion; and maternal mortality. Our outcome measures included (1) number of brachial plexus injuries or cases of incontinence averted, (2) incremental monetary cost per 100,000 deliveries, (3) expected quality of life of the mother and her child, and (4) "quality-adjusted life years" (QALY) associated with the two policies. For every 100,000 deliveries, the policy of elective C-section resulted in 16.6 fewer permanent brachial plexus injuries, 185.7 fewer cases of anal incontinence, and cost savings of $3,211,000. Therefore, this policy would prevent one case of anal incontinence for every 539 elective C-sections performed. The expected quality of life associated with the elective C-section policy was also greater (quality of life score 0.923 vs 0.917 on a scale from 0.0 to 1.0 and 53.6 QALY vs 53.2). A policy whereby primigravid patients in the United States have a 39 week ultrasound-estimated fetal weight followed by C-section for any fetuses ≥4500 g appears cost effective. However, the monetary costs in our analysis were sensitive to the *probability* estimates of urinary incontinence following C-section and vaginal delivery and the *cost* estimates for urinary incontinence, vaginal delivery, and C-section.

Keywords Elective cesarean section · Anal incontinence · Brachial plexus injuries · Macrosomia

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Introduction

As maternal and fetal mortality rates have steadily declined within the developed world [1], defining a "successful" childbirth has become increasingly centered upon issues of morbidity and quality of life from both the maternal and neonatal standpoints.

Especially with cases involving macrosomia, vaginal deliveries can result in significant injuries to both the mother and baby. Difficult vaginal childbirth has been implicated as the primary etiologic factor leading to pelvic floor disorders such as anal incontinence, urinary incontinence, and pelvic organ prolapse in the mother [2] as well as permanent brachial plexus injuries in the newborn [3]. Delivery via C-section (especially when the C-sections are performed in the absence of labor) tends to protect against such devastating maternal and neonatal injuries [4, 5, 6]. Thus, selective use of elective C-section (i.e., planned C-sections occurring prior to the onset of labor) may be a useful strategy to reduce both maternal and neonatal morbidity.

While recently there has been much debate in both the medical literature [7, 8, 9] and the lay press [10] regarding the use of elective C-section, the overall risks and benefits associated with elective C-section to prevent maternal and neonatal injuries have not been studied via traditional scientific research methods. Instead, clinical viewpoints regarding these issues have been shaped largely by opinion—with some clinicians and researchers advocating a woman's right to choose her delivery method [11] and others opposing the idea of "C-section on demand" due to possible increased risks [12] or costs relative to vaginal delivery.

While it would be difficult or impossible to carry out traditional scientific research (such as randomized clinical trials) to determine the optimal strategies regarding elective C-section, the technique of formal decision analysis is well suited for such studies [13, 14] because it explicitly considers each pertinent health outcome in terms of monetary costs and quality of life. Thus, decision analysis studies are effective when medical ethics or patient recruitment difficulties would make randomized clinical trials problematic or impossible.

Therefore, we used formal decision analysis to study the use of elective C-section for women believed to have very large fetuses. Our objective was to examine the cost-effectiveness of a policy whereby all primigravid patients in the United States would be offered an ultrasound at 39 weeks gestation followed by elective C-section for any estimated fetal weights ≥4500 g—in order to prevent maternal anal incontinence and neonatal brachial plexus injury.

Methods

A decision analytic model was developed to compare the cost-effectiveness of two policies for managing the delivery of primigravid patients: (1) current standard of care (i.e., spontaneous labor followed by either vaginal delivery or C-section as indicated) and (2) ultrasound at 39 weeks gestation followed by elective C-section for those women with estimated fetal weights of ≥4500 g. Consideration of those two policies for all primigravidas represented the two main branches of our decision tree. Diabetics and nondiabetics were considered independently. As the actual decision tree was too large for inclusion in this manuscript, a schematic version is provided (Fig. 1). The sub-branches of the tree represented possible clinical consequences of choosing either elective C-section or trial of labor. Chance events were entered into the model as dichotomous branch points or "nodes," and the probabilities assigned to each node were derived from the medical literature.

The major risks and/or complications considered crucial to the analysis were (1) brachial plexus injury to the newborn, (2) maternal anal incontinence (i.e., involuntary loss of stool and/or flatus), (3) maternal urinary incontinence, (4) emergency hysterectomy, (5) blood transfusion due to postpartum hemorrhage, and (6) maternal mortality. Due to the complexity and size of our decision tree, we did not consider other important but primarily transient conditions (such as endometritis or transient tachypnea of the newborn).

In accordance with the guidelines of the Panel on Cost-Effectiveness in Health and Medicine [15], we compared the elective C-section policy to the standard of care policy in terms of (1) absolute number of brachial plexus injuries or cases of anal incontinence averted, (2) incremental monetary cost per 100,000 deliveries, (3) expected quality of life of the mother and her child, and

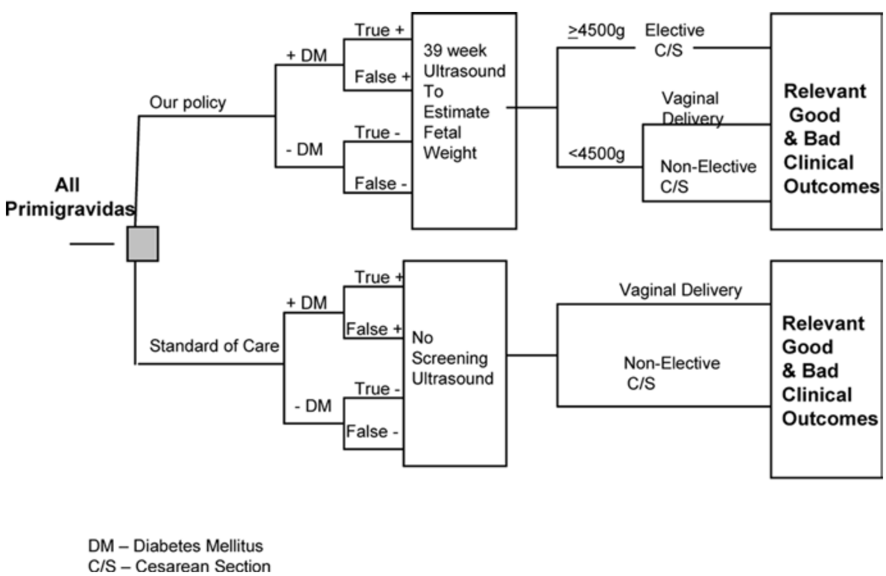

Fig. 1 Schematic version of the decision tree

(4) "quality-adjusted life years." The concept of quality-adjusted life years (QALY) considers the lifelong benefits of a healthcare policy by projecting these benefits over the life expectancy of the individual [16].

A panel of health care providers was selected to assign the utilities (i.e., quality of life scores) for each of the crucial risk/complication scenarios in the model. The members of this expert panel (Table 1) had diverse backgrounds and extensive experience dealing with the medical issues contained in the model. This panel met as a group to assign scores (Table 2) reflecting the quality of life associated with each combination of mother-newborn clinical scenarios (e.g., severe brachial plexus injury in a newborn whose mother developed anal incontinence, normal healthy child and mother with anal incontinence, etc.).

Our model dealt with two individuals at once, (i.e., the mother and the baby), so we combined their life expectancy into a "mother/baby dyad." To do so, we determined the average age of first-time mothers in the United States (24.3 years) [17], the life expectancy for those women (an *additional* 55.4 years) [18], and the life expectancy of a newborn in this country (weighted average of males and females = 76.85 years) [18]. Because people value health outcomes that occur over varying time periods differently, we discounted these life expectancies at a rate of 3% per annum as recommended by Weinstein [15].

We used Bayes' theorem to calculate the positive and negative predictive values of ultrasound to detect macrosomia. To test the robustness of our findings, we performed sensitivity analyses using plausible ranges on all probability, cost, and utility estimates. All analyses were performed using DATA 4.0 (TreeAge Software Inc., Boston, Mass., USA). More specific information regarding the components of our model is outlined below.

When conducting cost-effectiveness analyses, cost estimates depend upon the perspective (or viewpoint) used. In terms of decision analytic studies, the two most commonly used perspectives are *individual* (which considers costs of any single payer, patient, or provider) and *societal* (which represents the perspective of all persons affected by the intervention and is the one recommended by The Panel on Cost-Effectiveness in Health Medicine) [19].

Our methods for determining costs were derived from Medicare relative value unit coefficients and reimburse-

Table 1 Background, expertise, and gender of expert panel members

Background/expertise	Gender	Obstetric history
Urogynecology physician (attending)	Female	2 uncomplicated vaginal deliveries
Urogynecology physician (attending)	Male	NA
Urogynecology physician (fellow)	Male	NA
Urogynecology physician (fellow)	Female	1 elective C-section
OB-GYN physician (2nd year resident)	Female	1 vaginal delivery complicated by anal sphincter disruption (currently asymptomatic)
Urogynecology research RN	Female	2 uncomplicated vaginal deliveries
Maternal fetal medicine physician (attending)	Female	Nulliparous

Table 2 Utility (i.e., quality of life) estimates assigned by expert panel

Clinical condition of mother and child	Estimate	Plausible range
Uncomplicated vaginal delivery and healthy child	1.00	0.90–1.00
Vaginal delivery including 1st or 2nd degree episiotomy that heals normally and healthy child	0.995	0.90–1.00
Brachial plexus injury that resolves within 2 months	0.99	0.90–1.00
Hemorrhage requiring blood transfusion	0.96	0.90–1.00
3rd-4th anal sphincter disruption that heals well (asymptomatic)	0.85	0.75–0.95
Peripartum hysterectomy and healthy child	0.71	0.61–0.81
Urinary incontinence	0.70	0.60–0.80
Permanent brachial plexus injury (mild to moderate)	0.6000	0.50–0.70
Anal incontinence and healthy child	0.5000	0.40–0.65
Anal incontinence, peripartum hysterectomy, and healthy child	0.4900	0.35–0.65
Anal incontinence, urinary incontinence, and healthy child	0.4800	0.35–0.65
Anal incontinence and permanent brachial plexus injury (mild to moderate)	0.4600	0.30–0.60
Permanent brachial plexus injury (severe) and uncomplicated delivery	0.4500	0.30–0.60
Permanent brachial plexus injury (severe) and anal incontinence	0.3500	0.20–0.60
Permanent brachial plexus injury (severe), anal incontinence, and urinary incontinence	0.3400	0.20–0.60
Permanent brachial plexus injury (severe), anal incontinence, urinary incontinence, peripartum hysterectomy, and blood transfusion	0.3000	0.20–0.60
Maternal death	0.0300	0.00–0.10
Maternal death and brachial plexus injury that resolves within 2 months	0.0297	0.00–0.10
Maternal death and permanent brachial plexus injury (mild to moderate)	0.0180	0.00–0.10
Maternal death and permanent brachial plexus injury (severe)	0.0	0.0–0.10

ment rates using the societal perspective as described by Chung [20]. Total Medicare costs included the physician fee schedule, anesthesia fee schedule (where applicable), and the hospital payment (where applicable). We used the fee schedules for 2001 and the geographical practice cost for Louisville, KY [21]. The *total* costs used in the model are listed in Table 3. The components of the costs were as follows: a "complicated" delivery (either C-section or vaginal) included any combination of blood transfusion, hysterectomy and/or maternal death, and "uncomplicated" delivery included none of those three events. The cost of a transient brachial plexus injury included a hospital consultation by a specialist, physical therapy three times a week for 4 months, and one needle electromyography (EMG) test. The cost of a permanent, mild, or moderate brachial plexus injury included the costs of a transient injury plus one outpatient office visit to a specialist, continued physical therapy for 3 years, and magnetic resonance imaging (MRI) of the extremity and shoulder. The cost of a permanent, severe brachial plexus injury included all costs for a moderate injury plus one attempt at surgical correction. The cost of anal incontinence included one outpatient visit to a specialist, one ultrasound of the external anal sphincter, one external anal sphincteroplasty on all patients, and a repeat sphincteroplasty on 25% of those patients. The cost of urinary incontinence was determined by multiplying the average annual direct individual cost of urinary incontinence [22] by the life expectancy of the mother. Any costs that occurred over time were discounted at a rate of 3% per annum as recommended by Weinstein et al. [15].

We used a systematic approach to assign the probabilities within the model as follows: for each node, we read all pertinent articles retrieved from a MEDLINE search dating back to 1980. References listed in those articles were used to identify other pertinent articles not found in the original MEDLINE searches. Whenever possible, data from randomized clinical trials were used. When lesser medical evidence was used, priority was given to cohort studies, case-control studies, case series, and expert opinion, in that order. The probability estimates and plausible ranges used in our model are listed in Table 4. Some of the key estimates are presented below.

For nondiabetics and diabetics, the prevalence of actual birth weights ≥4500 g is 1.5 and 6.1%, respectively [23]. In nondiabetics, the sensitivity and specificity of ultrasound to detect a fetus weighing ≥4500 g are 58.5 and 91%, respectively. In diabetics, the sensitivity and specificity of ultrasound to detect a fetus weighing ≥4500 g are 57 and 94%, respectively [24, 25, 26]. These estimates were used to derive our main results. We also ran the model separately using a sensitivity estimate of 90%. We did this to account for the possibility that technological advances may improve our ability to detect macrosomia in the future.

When attempting a trial of labor for primigravid patients in the United States, the overall C-section rate is 19.3% [27]. For babies weighing ≥4500 g at birth, the C-section rate is 45% [28].

The prevalence of brachial plexus injury increases with increasing birth weight and is higher among diabetics. Among nondiabetics delivering vaginally, the prevalence is 0.065% for babies weighing <4000 g, 0.432% for babies weighing 4000–4499 g, and 2.14% for babies weighing ≥4500 g. Among diabetics, the prevalence rates following vaginal delivery are 0.18, 1.16, and 5.09% for babies weighing 4000 g, 4000–4499 g, and ≥4500 g, respectively [3].

Contrary to previous estimates [29], two recent longitudinal studies suggested that only 16.7% of all brachial plexus injuries spontaneously resolve [30, 31]. Of all brachial plexus injuries, approximately 27% are permanent and severe according to the Mallet [32] classification system, meaning that the affected arm will be essentially useless throughout life. Another 56% of these permanent injuries are at least moderate, meaning that the range of motion (abduction and/or rotation) in the affected arm will be limited to less than 30°. Only 0.6% of C-sections result in brachial plexus injuries of any kind [3].

Table 3 Cost estimates used in model

	Estimate (in US $)	Plausible range (in US $)
Immediate costs		
Repair of any episiotomy/laceration	10	0–25
39 week ultrasound	76	38–152
Brachial plexus injury (spontaneous resolution)	1440	720–2880
Anal incontinence	2927	1000–5854
Uncomplicated vaginal delivery	4187	2094–8374
Complicated vaginal delivery	5618	2809–11,236
Uncomplicated elective C-section	7361	3681–14,722
Complicated elective C-section	10,364	5182–20,728
Uncomplicated non-elective C-section	8740	4370–17,480
Complicated non-elective C-Section	12494	6247–24,988
Costs discounted over time		
Permanent brachial plexus injury (mild to moderate)	12868	6434–25,736
Permanent brachial plexus injury (severe)	14863	7432–29,726
Urinary incontinence	15059	7530–30,118

Table 4 Prevalence estimates used in the model

Clinical condition	Prevalence estimate	Plausible range	References
Anal incontinence following anal sphincter disruption	0.23	0.03–0.38	[37, 38]
Brachial plexus injury among infants ≥4500 g when gestational diabetes present	0.05	0.001–0.10	[3]
Brachial plexus injury among infants 4000–4499 g when gestational diabetes present	0.016	0.001–0.05	[3]
Brachial plexus injury among infants <4000 g when gestational diabetes present	0.002	0.001–0.01	[3]
Brachial plexus injury among infants ≥4500 g in the absence of gestational diabetes	0.02	0.001–0.10	[3]
Brachial plexus injury among infants 4000–4499 g in the absence of gestational diabetes	0.004	0.001–0.05	[3]
Brachial plexus injury among infants <4000 g in the absence of gestational diabetes	0.0007	0.0001–0.01	[3]
Brachial plexus injury following elective or non-elective C-section	0.0006	0.000001–0.03	[3, 50]
Chance that any brachial plexus injury will be permanent	0.83	0.05–0.9	[29, 30, 31]
Chance that a permanent brachial plexus injury will be severe[a]	0.27	0.05–0.50	[29, 30, 31]
Chance that a permanent brachial plexus injury will be moderate[b]	0.56	0.05–0.75	[29, 30, 31]
Chance that a brachial plexus injury will resolve	0.167	0.05–0.5	[29, 30, 31]
Hemorrhage requiring blood transfusion following vaginal delivery AND hysterectomy	0.14	0.02–0.75	[51]
Hemorrhage requiring blood transfusion following vaginal delivery WITHOUT hysterectomy	0.007	0.001–0.1	[49]
Hemorrhage requiring blood transfusion following elective C-section AND hysterectomy	0.14	0.02–0.75	[52]
Hemorrhage requiring blood transfusion following elective C-section WITHOUT hysterectomy	0.014	0.005–0.10	[50]
Hemorrhage requiring blood transfusion following NON-elective C-section AND hysterectomy	0.14	0.02–0.75	[50]
Hemorrhage requiring blood transfusion following NON-elective C-section WITHOUT hysterectomy	0.054	0.001–0.10	[50]
Maternal mortality following vaginal delivery	0.00004	0.00002–0.00005	[41]
Maternal mortality following elective C-section	0.000028	0.00002–0.00005	[41]
Maternal mortality following NON-elective C-section	0.0003	0.0001–0.001	[41]
Rate of episiotomy among primigravidas	0.41	0.25–0.50	[34, 35]
Peripartum hysterectomy following vaginal delivery	0.0002	0.0001–0.01	[40]
Peripartum hysterectomy following elective C-section	0.007	0.001–0.01	[40]
Peripartum hysterectomy following NON-elective C-section	0.007	0.001–0.01	[40]
Anal sphincter disruption when infant ≥4500 g WITHOUT episiotomy	0.16	0.05–0.25	[33, 34]
Anal sphincter disruption when infant 4000–4499 g WITHOUT episiotomy	0.11	0.01–0.25	[33, 34]
Anal sphincter disruption when infant <4000 g WITHOUT episiotomy	0.043	0.01–0.25	[33, 34]
Anal sphincter disruption when infant ≥4500 g WITH episiotomy	0.42	0.25–0.50	[33, 34]
Anal sphincter disruption when infant 4000–4499 g WITH episiotomy	0.32	0.20–0.50	[33, 34]
Anal sphincter disruption when infant <4000 g WITH episiotomy	0.15	0.10–0.50	[33, 34]
Non-elective C-section when infant ≥4500 g	0.45	0.30–0.70	[27, 28]
Non-elective C-section when infant 4000–4499 g	0.27	0.15–0.50	[27, 28]
Non-elective C-section when infant <4000 g	0.18	0.10–0.50	[27, 28]
Overall prevalence of gestational diabetes	0.03	0.01–0.09	[53]
Prevalence of infants weighing ≥4500 g among gestational diabetics	0.06	0.02–0.10	[54]
Prevalence of infants weighing 4000–4499 g among gestational diabetics	0.17	0.05–0.25	[54]
Prevalence of infants weighing <4000 g among gestational diabetics	0.77	0.50–0.90	[54]
Prevalence of infants weighing ≥4500 g among nondiabetics	0.015	0.005–0.03	[54]
Prevalence of infants weighing 4000–4499 g among nondiabetics	0.082	0.03–0.10	[54]
Prevalence of infants weighing <4000 g among nondiabetics	0.9	0.75–0.99	[54]
Sensitivity of test for gestational diabetes	0.99	0.90–0.9950	[54]
Specificity of test for gestational diabetes	0.66	0.50–0.80	[54]
Sensitivity of ultrasound to detect macrosomia among gestational diabetics	0.57	0.50–0.95	[24, 25, 26]
Specificity of ultrasound to detect macrosomia among gestational diabetics	0.94	0.75–0.95	[24, 25, 26]
Sensitivity of ultrasound to detect macrosomia among nondiabetics	0.59	0.50–0.95	[24, 25, 26]
Specificity of ultrasound to detect macrosomia among nondiabetics	0.91	0.75–0.95	[24, 25, 26]
Urinary incontinence following 1st vaginal delivery	0.25	0.05–0.30	[40]
Urinary incontinence following 1st elective C-section	0.05	0.01–0.30	[40]
Urinary incontinence following 1st non-elective C-section	0.12	0.05–0.30	[40]

[a]Mallet [32] class less than 3
[b]Mallet [32] class 3 to 4

The use of both episiotomy and operative vaginal delivery significantly increases the risk of anal sphincter disruption [33]. Vacuum and/or forceps are used in approximately 19% of vaginal deliveries involving macrosomic infants [34] and episiotomies are incorporated in 40.6% of all primigravid deliveries [35, 36]. Forceps tend to damage the pelvic floor more often than vacuums [37]. Due to the inherent subjectivity associated with choosing between forceps and vacuum use, we chose to account for episiotomy but *not* operative delivery in our analysis. In other words, rather than inject bias into the decision tree by arbitrarily choosing a rate of forceps vs vacuum use, we decided to leave operative vaginal delivery out of the model entirely.

Therefore, when choosing the prevalence estimates for anal sphincter disruption used in our model, we assumed that the baseline rate of anal sphincter disruption (i.e., in the absence of macrosomia) with and without episiotomy were 14.8 and 4.3%, respectively [35]. We then used the odds ratios reported by Angioli [33] to arrive at the likelihood of anal sphincter disruption associated with macrosomia (Table 4).

If a woman sustains a third- or fourth-degree anal sphincter disruption, the likelihood that she will experience chronic anal incontinence is 23% [38, 39]. For the purposes of our model, we assumed that anal incontinence would not happen in the absence of an anal sphincter disruption.

The prevalence rates of urinary incontinence among primiparous patients who undergo elective C-section, non-elective C-section, and spontaneous vaginal delivery are 5, 12, and 24.5%, respectively [40].

Emergency postpartum hysterectomies are performed after 0.02% of vaginal deliveries and 0.7% of C-sections [41]. We could not find specific information regarding the rates of postpartum hysterectomy for elective and non-elective primary C-sections, so for the purposes of the model we assumed they were equal.

The maternal mortality rates (expressed in deaths per 100,000 births) associated with vaginal delivery, elective C-section, and non-elective C-section are 3.6, 2.8, and 30.0 respectively [42].

Sensitivity analyses were performed to assess the robustness of the model. The value of each probability, utility, and cost estimate was varied within a plausible range to determine if there was a point at which the preferred strategy changed from the proposed 4500 g screening policy to standard of care. These one-way sensitivity analyses were performed separately with respect to effectiveness and cost. With respect to effectiveness, a variable was considered to have a threshold if its variation in the model caused the standard of care approach to win out in terms of quality of life. With respect to cost, a variable was considered to have a threshold if its variation within the model caused the standard of care approach to win out in terms of monetary cost. These sensitivity analyses (rather than p-values and confidence intervals) provide the inferential strategy within decision analysis studies.

Results

For every 100,000 deliveries, adopting the policy of near-term ultrasound followed by elective C-sections for fetuses believed to weigh ≥ 4,500 grams resulted in 185.7 fewer cases of maternal anal incontinence and 16.6 fewer cases of permanent neonatal brachial plexus injury than the current standard of care. Thus under the new policy, one case of anal incontinence would be prevented for every 539 elective C-sections performed, and one permanent brachial plexus injury would be prevented for every 6,024 elective C-sections performed.

For every 100,000 deliveries, the standard of care policy cost \$850,581,000 and the elective C-section policy cost \$847,370,000. Thus, the new policy resulted in a cost *savings* of \$3,211,000 for every 100,000 deliveries.

The expected quality of life – for the mother/newborn dyad – of the elective C-section policy was higher than that for the current standard of care (0.923 vs 0.917 on a scale from 0.0 to 1.0). The standard of care approach resulted in 53.2 QALY and the 4500 g screening policy resulted in 53.6 QALY. Thus the selective use of elective C-section as proposed in our model resulted in a higher quality of life per delivery at lower monetary costs.

Separate analyses for diabetic women revealed similar, slightly more compelling results. Among diabetics, the elective C-section policy saved \$6,375,000 per 100,000 deliveries; resulted in an added quality of life of 0.006 (0.922 vs 0.928 on a scale from 0.0 to 1.0), and resulted in an additional 0.33 QALY for the mother-infant dyad. Even when non-diabetics were considered alone, the elective C-section won out in terms of cost and effectiveness. Among non-diabetics, the elective C-section policy saved \$3,113,000 per 100,000 deliveries; resulted in an added quality of life of 0.006 (0.917 versus 0.923), and resulted in an additional 0.37 QALY for the mother/newborn dyad.

If the sensitivity of ultrasound to detect macrosomia could be improved from 58.5% to 90% (chosen arbitrarily) the proposed elective C-section policy would result in an even greater cost savings of \$3,827,000 per 100,000 deliveries and an additional 0.40 QALY for the mother/newborn dyad.

None of the estimates of probability or utility reached a threshold within wide plausible ranges when the focus was on effectiveness (or QALY gained). The model was very robust: the proposed 4500 g screening strategy clearly results in (1) fewer cases of permanent brachial plexus injury to the newborn, (2) fewer cases of maternal anal incontinence, (3) a higher quality of life for the mother-infant dyad, and (4) more QALYs for the mother-infant dyad.

None of the quality of life *utilities* manifested a threshold when the outcome was monetary costs, and only two of the *probability* estimates manifested a threshold. Those probability estimates were (1) the probability of urinary incontinence resulting from a vaginal delivery; and (2) the probability of urinary incontinence resulting from an elective C-section. Our estimate for the probability of urinary incontinence resulting from a vaginal delivery was 0.245; if this probability decreased to 0.217, a threshold would be reached and the monetary costs would be equal for the two policies. Our estimate for the probability of urinary incontinence resulting from an elective C-section was 0.05; if that estimate were raised to 0.072, a similar cost threshold would be reached. Therefore, the monetary costs in our analysis were sensitive to the *probability* estimates of these two outcomes of urinary incontinence.

There were four *cost* estimates that reached a threshold amid very wide plausible ranges. Those were the costs associated with (1) urinary incontinence, (2) uncomplicated vaginal delivery, (3) uncomplicated elective C-section, and (4) uncomplicated non-elective C-section. If the current costs associated with urinary incontinence could be lowered by 13 percent (from $15,059 to $13,100), or if the cost of vaginal delivery were lowered by 10 percent (from $4,187 to $3,764), then the standard of care policy would be less costly.

The cost of an uncomplicated non-elective C-section would have to decrease 19% (from $8,740 to $7,092) to reach a cost threshold, and the cost of an uncomplicated elective C-section would have decrease 4% (from $7,699 to $7,361) to reach a cost threshold.

Although urinary incontinence was not the major focus of this analysis, we performed a "special" sensitivity analysis regarding this condition. We did this because the outcome of our model was sensitive to the prevalence of this condition. To do so, the entire cost-effectiveness analysis was conducted with the probability of urinary incontinence (for vaginal delivery and both types of C-section) set to zero. In other words, we ran the analysis as though urinary incontinence were irrelevant to our decision-making goals. Doing so put the focus of the analysis on anal incontinence and brachial plexus injury. With urinary incontinence removed from the model entirely, the elective C-section policy still won out in terms of QALY—with an incremental gain of 0.112 per delivery. However, doing so also resulted in higher costs—with the elective C-section policy costing $21,432,000 more per 100,000 deliveries than the standard of care policy. In that scenario, the elective C-section policy would cost an additional $1,921 per QALY gained.

Discussion

The optimal delivery strategy for suspected macrosomic infants must include a balanced consideration of economic costs, morbidity, mortality, and overall quality of life for the mother and baby. Formal decision analysis is a powerful method for guiding clinical decision making by incorporating all of these factors. When a proposed strategy proves both less costly and better in terms of quality of life, it should be considered "dominant" and adopted as a public policy [43]. Our policy of elective C-section for babies believed to weigh ≥4500 g met these criteria. With respect to *effectiveness*, our model was completely robust to any estimates of probability, utility, and cost within wide plausible ranges. With respect to *costs,* our analysis was robust to all of the estimates of probability, utility, and all costs with the important exceptions of costs for urinary incontinence and the costs of the various delivery modes.

However, even when urinary incontinence was completely removed from the model (thereby maximizing its negative impact on the elective C-section policy), the 4500-g screening strategy remained optimal in terms of QALY. In that scenario, the elective C-section policy would cost $1921 per QALY gained. According to Owens [44], a proposed healthcare policy should be considered cost effective if it requires an incremental cost of less than $50,000 to "purchase" one additional QALY. More recently, even this $50,000 threshold has been challenged [45] for being too low. Therefore, even with urinary incontinence removed from the model, the elective C-section policy was highly cost effective by these standards.

Although the long-term sequelae associated with difficult vaginal deliveries represent a major public health issue, highly prevalent and debilitating conditions such as anal incontinence have rarely been factored into policies that guide obstetrical practices. Anal incontinence has significant negative effects on sexuality, exercise, social activities, and work activities, and is directly associated with depression [46]. The poor quality of life score assigned by our expert panel to the outcome of anal incontinence reflected these potential lifelong repercussions.

Vaginal childbirth, occurring without significant short- or long-term complications, is clearly the outcome of choice among obstetric care providers and patients alike. Within the current standard of care, C-sections are primarily offered when attempts at vaginal delivery are impractical or fail. As such, C-sections are most commonly viewed as a second choice. Unfortunately, it is impossible to accurately predict all individual adverse events associated with attempted vaginal childbirth. Although our ability to evaluate and treat pelvic floor disorders such as anal incontinence continues to improve, little progress has been made in the area of primary prevention. Elective C-section is a logical primary preventive strategy when reserved for patients at particularly high risk for the sequelae of vaginal childbirth. Women with macrosomic fetuses represent one such risk group.

Any policy that would result in higher overall C-section rates is met with understandable skepticism. However, the argument for reducing C-section rates is predicated on the belief that they are always more costly, more lethal, and more morbid than vaginal deliveries. When debating these issues, the concept of "intent to treat" warrants careful consideration. C-sections performed electively in the absence of labor should be distinguished from those performed after a trial (or "intention") of labor. Recent evidence suggests that C-sections performed electively before the onset of labor compare favorably to vaginal delivery in terms of safety and cost [47, 48]. Thus, when vaginal delivery is attempted unsuccessfully, a significant degree of any morbidity or mortality associated with C-sections should be attributed to the original decision to attempt vaginal delivery. In other words, it is possible that a significant proportion of these problems would have been avoided if the C-section had been performed electively. The technique of formal decision analysis allowed for the comparison of two obstetrical strategies from an intent to treat perspective.

Ours is not the first decision analysis regarding elective C-section for macrosomic infants. In 1996, Rouse [28] used a decision analytic model to examine a policy whereby infants with ultrasonically detected macrosomia would be delivered via elective cesarean section to prevent brachial plexus injuries alone. These authors described such a policy as economically unsound due to both the low incidence of brachial plexus injuries and the poor predictive value of ultrasonic estimated fetal weight. Their analysis differed from ours in several ways: (1) they chose not to consider maternal pelvic floor disorders (nor any other maternal morbidity associated with macrosomia) or any quality of life estimates, (2) their estimates for the number of infants who would experience spontaneous resolution of their brachial plexus disorders [29] were considerably higher than the estimates we used [30, 31], and (3) their monetary cost estimates were calculated differently than ours. Specifically, their cost estimates were not based on the Medicare relative value unit coefficients and reimbursement rates.

Recognizing that a decision analysis model is subject to the biases of its creator, we consistently chose assumptions that would tend to bias the analysis *against* the use of elective C-section. Nevertheless, there are several limitations to our study. First and foremost, a reader must decide to accept the validity of our utility scores before he/she can accept the validity of our conclusions.

Also, our model only considers a woman's first delivery; therefore, it does not consider the impact of future C-sections or attempted vaginal births. An individual woman's risk of placenta previa—and therefore the chance of significant hemorrhage and/or emergency hysterectomy—increases with an increased number of C-sections [49]; leaving future deliveries out of the model undoubtedly enhanced the desirability of the elective C-section policy. Thus, the policy we suggest may not be ideal for patients planning large families.

We chose not to include certain short-term morbidities typically associated with both C-sections and vaginal deliveries such as wound infections, urinary tract infections, and thromboembolic disease. Assuming these morbidities are disproportionately associated with C-sections performed after a trial of labor, their inclusion would have further enhanced the desirability of the elective C-section policy in our model. Thus, our decision to exclude these factors was a "conservative" one—favoring the standard of care policy.

We made other "conservative" choices regarding the causes of anal incontinence and the use of vacuum or forceps. For the purposes of this model, a woman could only develop anal incontinence if she sustained a third- or fourth-degree anal sphincter disruption during a vaginal delivery. In reality, some patients develop anal incontinence after both uncomplicated vaginal deliveries and C-sections, but again higher proportion of these cases occur following vaginal birth [34]. Therefore, including estimates for anal incontinence following all types of deliveries would have made the elective C-section policy even more desirable. Similarly, as mentioned in the "Methods" section, our decision to assume that no forceps or vacuums were used caused us to underestimate the desirability of elective C-section within the model.

Our methods for deriving costs also tended to underestimate the savings associated with the elective C-section policy. Whereas the direct lifetime costs of urinary incontinence have been previously reported [22] and were included in the model, no similar data exist with regard to anal incontinence. Therefore, our model vastly underestimated the costs of anal incontinence, as we only considered the immediate direct costs (within 12 months of the anal sphincter injury) of this potentially lifelong condition. The same is true of the estimate of brachial plexus injury costs, because we only considered the first 3 years of an affected child's life. Furthermore, despite the clear medicolegal ramifications of anal sphincter and brachial plexus injuries, no such costs were included in our analysis. While including those costs in the model would have favored the elective C-section policy, doing so would have increased the model's subjectivity—leaving it more vulnerable to scrutiny.

In conclusion, as the debate surrounding obstetrical choices evolves relative to the concept of informed consent, our findings may provide useful insight for the subset of women believed to be carrying macrosomic fetuses. Our analysis suggests that a policy whereby all primigravid patients in the United States would undergo an ultrasound at 39 weeks gestation, followed by an elective C-section for any fetus estimated at ≥4500 g, would be cost effective. Recognizing the widespread implications of adopting such a policy (including the extra time and effort that will be required of obstetric practitioners during the informed consent process), we advocate the addition of "delivery mode counseling" codes to the Medicare physician fee schedule with reimbursement rates that accurately reflect the resultant efforts of obstetric practitioners.

Contributions of authors Dr. Culligan conceived of the idea, reviewed all of the referenced articles, helped with the tree design, and wrote the manuscript. Mr. Myers built the tree using the TreeAge software under the guidance of his professor, Dr. Abell. Dr. Abell served as mentor to Mr. Myers and built a significant portion of the tree himself. Dr. Gohmann performed the economic analysis and served as a consultant regarding cost analysis. Ms. Blackwell performed the initial literature searches for all nodes within the tree. Dr. Goldberg assisted in development of the concept for the study and aided in the manuscript preparation.

References

1. Centers for Disease Control and Prevention (1999) Healthier mothers and babies. MMWR Morb Mortal Wkly Rep 48:849–857
2. Handa VL, Harris TA, Ostergard DR (1996) Protecting the pelvic floor: obstetric management to prevent incontinence and pelvic organ prolapse. Obstet Gynecol 88:470–477
3. Ecker JL, Greenberg JA, Norwitz ER, Nadel AS, Repke JT (1997) Birth weight as a predictor of brachial plexus injury. Obstet Gynecol 89:643–647
4. Moalli PA, Ivy SJ, Meyn LA, Zyczynski (2003) Risk factors associated with pelvic floor disorders in women undergoing surgical repair. Obstet Gynecol 101:869–874
5. Rortveit G, Daltveit AK, Hannestad YS, Hunskaar S (2003) Urinary incontinence after vaginal delivery or Cesarean section. N Engl J Med 348:900–907
6. MacArthur C, Glazener, Wilson PD, Herbison GP, Gee H, Lang GD, Lancashire R (2001) Obstetric practice and faecal incontinence three months after delivery. Br J Obstet Gynaecol 108:678–683
7. Sand PK, Grobman W (2002) Scholarly debate: prophylactic benefits of elective Cesarean delivery/broad-based conversion to elective Cesarean delivery is not justified. Female Patient 27:18–28
8. O'Boyle AL, Davis GD, Calhoun BC (2002) Informed consent and birth: protecting the pelvic floor and ourselves. Am J Obstet Gynecol 187:981–983
9. Bewley S, Cockburn J (2002) The unethics of 'request' caesarean section. Br J Obstet Gynaecol 109:593–596
10. Snowbeck C (2003) Is elective C-section delivery a good idea? Pittsburg Post-Gazette, 18 March 2003
11. Davila GW (2001) Informed consent for obstetrics management: A urogynecologic perspective. Int Urogynecol J 12:289–291
12. Bewley S, Cockburn J (2002) The unfacts of 'request' caesarean section. Br J Obstet Gynaecol 109:597–605
13. Sox HC, Blatt MA, Higgins MC (1988) Medical decision making. Butterworth-Heinemann, Boston
14. Weinstein MC, Fineberg HV (1980) Clinical decision analysis. WB Saunders, Philadelphia
15. Weinstein MC, Siegel JE, Gold MR, Kamlet MS, Russell LB (1996) Recommendations of the panel on cost-effectiveness in health and medicine. JAMA 276:1253–1258
16. Drummond MF, O'Brien B, Stoddart GL, Torrance GW (1997) Methods for the economic evaluation of health care programmes, 2nd edn. Oxford University Press, New York
17. Centers for Disease Control and Prevention/National Center for Health Statistics (1997) Series 23—No. 19. Fertility, family planning, and women's health: New data from the 1995 national survey of family growth, May 1997
18. Centers for Disease Control and Prevention/National Center for Health Statistics (1999) Vol 49, No. 12. Life expectancy at single years of age, United States, 1999
19. Russell LB, Gold MR, Seigel JE, Daniels N, Weinstein MC (1996) The role of cost-effectiveness analysis in health and medicine. JAMA 276:1172–1177
20. Chung KC, Walters MR, Greenfield MH, Chernew ME (1998) Endoscopic versus open carpal tunnel release: a cost-effectiveness analysis. Plast Reconstr Surg 102:1089
21. Department of Health and Human Services Federal Register, Medicare Program (2001) Changes to the hospital inpatient prospective payment systems and physician fee schedule. Fiscal year 2002 rates, final rules, 1 August 2001
22. Wilson L, Brown JS, Shin GP, Luc KO, Subak LL (2001) Annual direct cost of urinary incontinence. Obstet Gynecol 98:398–406
23. Ventura SJ, Martin JA, Curtin SC, Menacker F, Hamilton BE (2001) Births: final data for 1999. National Vital Statistics Report 49(1):1–76
24. Chervenak JL, Divon MY, Hirsch J, Girz BA, Langer O (1989) Macrosomia in the postdate pregnancy: is routine ultrasonographic screening needed? Am J Obstet Gynecol 161:753–756
25. McLaren RA, Puckett JL, Chauhan SP (1995) Estimators of birth weight in pregnant women requiring insulin: a comparison of seven sonographic models. Obstet Gynecol 85:565–569
26. Pollack RN, Hauer-Pollack G, Divon MY (1992) Macrosomia in postdates pregnancies: the accuracy of routine ultrasonographic screening. Am J Obstet Gynecol 167:7–11
27. Braveman P, Egerter S, Edmonston F, Edmonston F, Verdon M (1995) Racial/ethnic differences in the likelihood of cesarean delivery, California. Am J Pub Health 85:625–630
28. Rouse DJ, Owen J, Goldenberg RL, Cliver SP (1996) The effectiveness and costs of elective cesarean delivery for fetal macrosomia diagnosed by ultrasound. JAMA 276:1480–1486
29. Gordon M, Rich H, Deutschberger WL, Green M (1973) The immediate and long-term impact of obstetric birth trauma. Am J Obstet Gynecol 117:51–56
30. Waters PM (1999) Comparison of the natural history, the outcome of microsurgical repair, and the outcome of operative reconstruction in brachial plexus palsy. J Bone Joint Surg Am 81:649–659
31. Hoeksma AF, Wolf H, Oei SL (2000) Obstetrical brachial plexus injuries: incidence, natural course and shoulder contracture. Clin Rehab 14:523–526
32. Mallet J (1972) Primaute du traitement de l'epaule—methods d'expression des resultats. Rev Chir Orthop 58 [Suppl 1]:166–168
33. Angioli R, Gomez-Martin O, Cantuaria G, O'Sullivan MJ (2000) Severe perineal lacerations during vaginal delivery: the University of Miami experience. Am J Obstet Gynecol 182:1083–1085
34. Kolderup LB, Laros RK, Musci TJ (1997) Incidence of persistent birth injury in macrosomic infants: association with mode of delivery. Am J Obstet Gynecol 177:37–41
35. Robinson JN, Norwitz ER, Cohen AP, Lieberman E (2000) Predictors of episiotomy use at first spontaneous vaginal delivery. Obstet Gynecol 96:214–218
36. Fraser WD, Marcoux S, Krauss I, Douglas J, Goulet C, Boulvain M, et al. (2000) Multicenter, randomized, controlled trial of delayed pushing for nulliparous women in the second stage of labor with continuous epidural anesthesia. Am J Obstet Gynecol 182:1165–1172
37. Arya LA, Jackson ND, Meyers DL, Verma A (2001) Risk of new-onset urinary incontinence after forceps and vacuum delivery in primiparous women. Am J Obstet Gynecol 185:1318–1324
38. Fitzpatrick M, Behan M, O'Connell PR, Herlihy (2000) A randomized clinical trial comparing primary overlap with approximation repair of third-degree obstetric tears. Am J Obstet Gynecol 183:1220–1224
39. Abramowitz L, Sobhani I, Ganansia r, Vuagnat A, Benifla JL, Darai E, et al. (2000) Are sphincter defects the cause of anal incontinence after vaginal delivery? Dis Col Rect 43:590–598
40. Farrell SA, Allen VM, Baskett TF (2001) Parturition and urinary incontinence in primiparas. Obstet Gynecol 97:350–356
41. Clark SL, Yeh S, Phelan JP, Bruce S, Paul RH (1984) Emergency hysterectomy for obstetric hemorrhage. Obstet Gynecol 64:376–380
42. Yoles L, Maschiach S (1998) Increased maternal mortality in cesarean section as compared to vaginal delivery? Time for reevaluation. Am J Obstet Gynecol 178 [Suppl 1]:78s

43. Laupacis A, Feeny D, Detsky A, Tugwell PX (1992) How attractive does a new technology have to be to warrant adoption and utilization? Tentative guidelines for using economic evaluations. Can Med Assoc J 146:473–481
44. Owens DK (1998) Interpretation of cost-effectiveness analyses. J Gen Intern Med 13:716–717
45. Ubel PA, Hirth RA, Chernew ME, Fendrick MA (2003) What is the price of life and why doesn't it increase at the rate of inflation? Arch Int Med 163:1637–1641
46. Whitehead WE, Wald A, Norton NJ (2001) Treatment options for fecal incontinence—consensus conference report. Dis Colon Rectum 44:131–144
47. Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR (2000) Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomized multicenter trial. Lancet 356:1375–1383
48. Bost BW (2002) The economic impact of cesarean delivery on demand. Obstet Gynecol 99:86s
49. Gilliam M, Rosenberg D, Davis F (2002) The likelihood of placenta previa with greater number of Cesarean deliveries and higher parity. Obstet Gynecol 99:976–980
50. Gilbert WM, Nesbit TS, Danielsen B (1999) Associated factors in 1611 cases of brachial plexus injury. Obstet Gynecol 93:536–540
51. Combs AC, Murphy EL, Laros RK (1991) Factors associated with postpartum hemorrhage with vaginal birth. Obstet Gynecol 77:69–76
52. Combs CA, Murphy EL, Laros RK (1991) Factors associated with hemorrhage in cesarean deliveries. Obstet Gynecol 77:77–82
53. American College of Obstetricians and Gynecologists (2001) Practice bulletin #30, September 2001
54. Sarno AP Jr, Hinderstein WN, Staiano RA (1991) Fetal macrosomia in a military hospital: incidence, risk factors and outcome. Mil Med 156:55–58

Editorial comment

This is an interesting decision analysis looking at a unique method for determining who would be a candidate for an elective cesarean section. In this decision analysis, all patients have an ultrasound at 39 weeks estimated gestational age (EGA) and if it is estimated that the fetal weight is greater than 4500 g, that patient would be recommended for an elective cesarean section. This would then be a cost-effective way of reducing the risk of brachial plexus injury to the infant and reduce the risk of fecal incontinence. One of the most fascinating aspects of this paper is that even though they looked at this as a strategy to prevent urinary incontinence, they could not show that this would significantly reduce the incidence of urinary incontinence. This together with several other large epidemiologic studies are starting to cast doubt on the strategy of elective cesarean section to prevent urinary incontinence. One of the questions that always surfaces after reviewing this type of article is that while we can pick out specific diseases such as brachial plexus injury and anal incontinence, it is difficult to determine the impact of all the other potential complications and benefits. Until a large prospective randomized trial is done comparing a strategy of offering patients elective cesarean versus planned vaginal delivery, it will be impossible to know what the real impact of elective cesarean sections will be.