Universal Urogynecologic Consultation and Screening for Fecal Incontinence in Pregnant Women With a History of Obstetric Anal Sphincter Injury: A Cost-Effectiveness Analysis

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Importance Obstetric anal sphincter injuries (OASIS) predispose for the development of fecal incontinence (FI), but management of subsequent pregnancy after OASIS is controversial.

Objective We aimed to determine if universal urogynecologic consultation (UUC) for pregnant women with prior OASIS is cost-effective.

Study Design We performed a cost-effectiveness analysis of pregnant women with a history of OASIS modeling UUC compared with no referral (usual care). We modeled the route of delivery, peripartum complications, and subsequent treatment options for FI. Probabilities and utilities were obtained from published literature. Costs using a third-party payer perspective were gathered from the Medicare physician fee schedule reimbursement data or published literature converted to 2019 U.S. dollars. Cost-effectiveness was determined using incremental cost-effectiveness ratios).

Results Our model demonstrated that UUC for pregnant patients with prior OASIS was cost-effective. Compared with usual care, the incremental cost-effectiveness ratio for this strategy was $19,858.32 per quality-adjusted life-year, below the willingness to pay a threshold of $50, 000/quality-adjusted life-year. Universal urogynecologic consultation reduced the ultimate rate of FI from 25.33% to 22.67% and reduced patients living with untreated FI from 17.36% to 1.49%. Universal urogynecologic consultation increased the use of physical therapy by 14.14%, whereas rates of sacral neuromodulation and sphincteroplasty increased by only 2.48% and 0.58%, respectively. Universal urogynecologic consultation reduced the rate of vaginal delivery from 97.26% to 72.42%, which in turn led to a 1.15% increase in peripartum maternal complications.

Conclusions Universal urogynecologic consultation in women with a history of OASIS is a cost-effective strategy that decreases the overall incidence of FI, increases treatment utilization for FI, and only marginally increases the risk of maternal morbidity.

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WHY THIS MATTERS

- Obstetric anal sphincter injuries (OASIS) predispose to the development of fecal incontinence (FI), which has significant medical, psychosocial, and financial consequences for patients, caregivers, and the health care system. Management of subsequent pregnancy after OASIS is controversial and difficult to study with clinical trials. We aimed to determine if universal urogynecologic consultation for pregnant women with prior OASIS is cost-effective. We constructed a decision tree model, including mode of delivery, peripartum maternal morbidity, and FI treatment options. Our model demonstrated that universal urogynecologic consultation is a cost-effective strategy that decreases the overall incidence of FI, increases the utilization of treatment for FI, and only marginally increases the risk of maternal morbidity.

Fecal incontinence (FI) is the involuntary passage of solid or liquid stool from the rectum, which often has devastating effects on the patient's quality of life. Incontinence events and their anticipation can damage both psychosocial well-being and intimate relationships.[1,2] Anxiety around the potential for an incontinence event outside the home can result in isolation due to avoidance of social situations.[1,2] One systematic review estimated the prevalence of FI to range from 1.4% to 19.5%, although the physical and psychological distress of FI may cause reluctance to seek medical evaluation, leading to an underestimate of the true prevalence.[3]

Risk factors for FI include age, obesity, abnormal stool consistency, pregnancy/parity, prolapse, and neurologic factors.[1,2,4,5] Among women who develop postpartum FI, obstetric anal sphincter injuries (OASIS) contribute to about half of the cases.[1,5] Obstetric anal sphincter injuries include third- and fourth-degree perineal lacerations that disrupt the anal sphincter.[6] Risk factors for OASIS include forceps-assisted vaginal delivery, episiotomy, prolonged labor, older maternal age, and obesity.[1,4,7,8] Fecal incontinence is estimated to increase per-person health care expenditure by 55% or about $2,897 per year, accounting for $11 billion annually in the United States.[1,9] Increased health care expenditure for FI includes direct costs of clinic visits, hospital fees, medications, and treatment supplies as well as indirect costs such as impact on employment, caregiver assistance, and placement in assisted living facilities.[1,2]

In women with prior OASIS, management of subsequent pregnancy is controversial. There is no consensus regarding whether cesarean delivery (CD) should be recommended as primary prevention of future FI.[1,7,8,10–12] There is evidence that subsequent CD may have long-term protective benefits for patients with prior OASIS, and patients should be counseled on the risks and benefits of an elective CD (ECD) as opposed to vaginal delivery.[8,10] Currently, no data exist on whether there is a cost impact from a policy of universal urogynecologic consultation (UUC) for screening and treatment for FI in subsequent pregnancies after OASIS. Considering the high economic burden of FI, UUC for patients with prior OASIS with subsequent screening for FI and with counseling on delivery options and postpartum treatment may result in better long-term outcomes. Therefore, the objective of this study is to determine if UUC for pregnant women with a history of OASIS is cost-effective.

MATERIALS AND METHODS

This study was evaluated by the Yale University Institutional Review Board and determined not to be human subject research and thus was exempt from formal review. We performed a cost-effectiveness analysis using TreeAge Pro (Williamstown, Massachusetts). A simplified diagram of the decision tree is depicted in Figure 1. For pregnant women with a history of OASIS in a previous delivery, we modeled UUC. After screening, patients were counseled on risks of new-onset/worsening FI based on delivery route. We compared ECD versus trial of labor with subsequent vaginal delivery or CD in labor. This was compared with "usual care" without FI screening and subsequent trial of labor.

We also modeled the probabilities of various peripartum maternal complications. We included the complications of death, transfusion, venous thromboembolism, surgical injury (bladder or uterine injury), infection (wound infection or endometritis), and peripartum hysterectomy. Probabilities varied depending on the mode of delivery, with CD in labor generally having the highest rate of complications and vaginal delivery having the lowest (Table 1).

The third subtree modeled the treatment options for those patients with ongoing or newly developed FI. For the purposes of this study, first-line treatment was defined as pharmacological therapy and pelvic floor physical therapy. Second-line treatment was defined as either anal sphincteroplasty or sacral neuromodulation (SNM). We allowed for the option of starting with either sphincteroplasty or SNM with an assumed 50–50 split in patient preference. This 50–50 split was varied across the entire range from 0–100 to 100–0 in sensitivity analysis to ensure it was not affecting our outcomes. If the patient failed second-line treatment, they then had the option to try the alternate second-line treatment (sphincteroplasty or SNM) as their third-line treatment option.

Probabilities used in the model were obtained from the published literature using PubMed to find relevant primary sources. When multiple high-quality studies indicated different probabilities of an event occurring, the probability used in the model was a weighted mean of all studies. Table 1 shows the weighted probabilities of events included in the model. Because of lack of existing high-quality evidence, we assumed that CD was protective against development for FI. Women who did not have FI after their first delivery would not develop de novo FI after ECD. With vaginal delivery, new onset of FI was modeled according to published literature.

Our model used utilities and quality-adjusted life-years (QALYs) as the effectiveness variable. Utilities

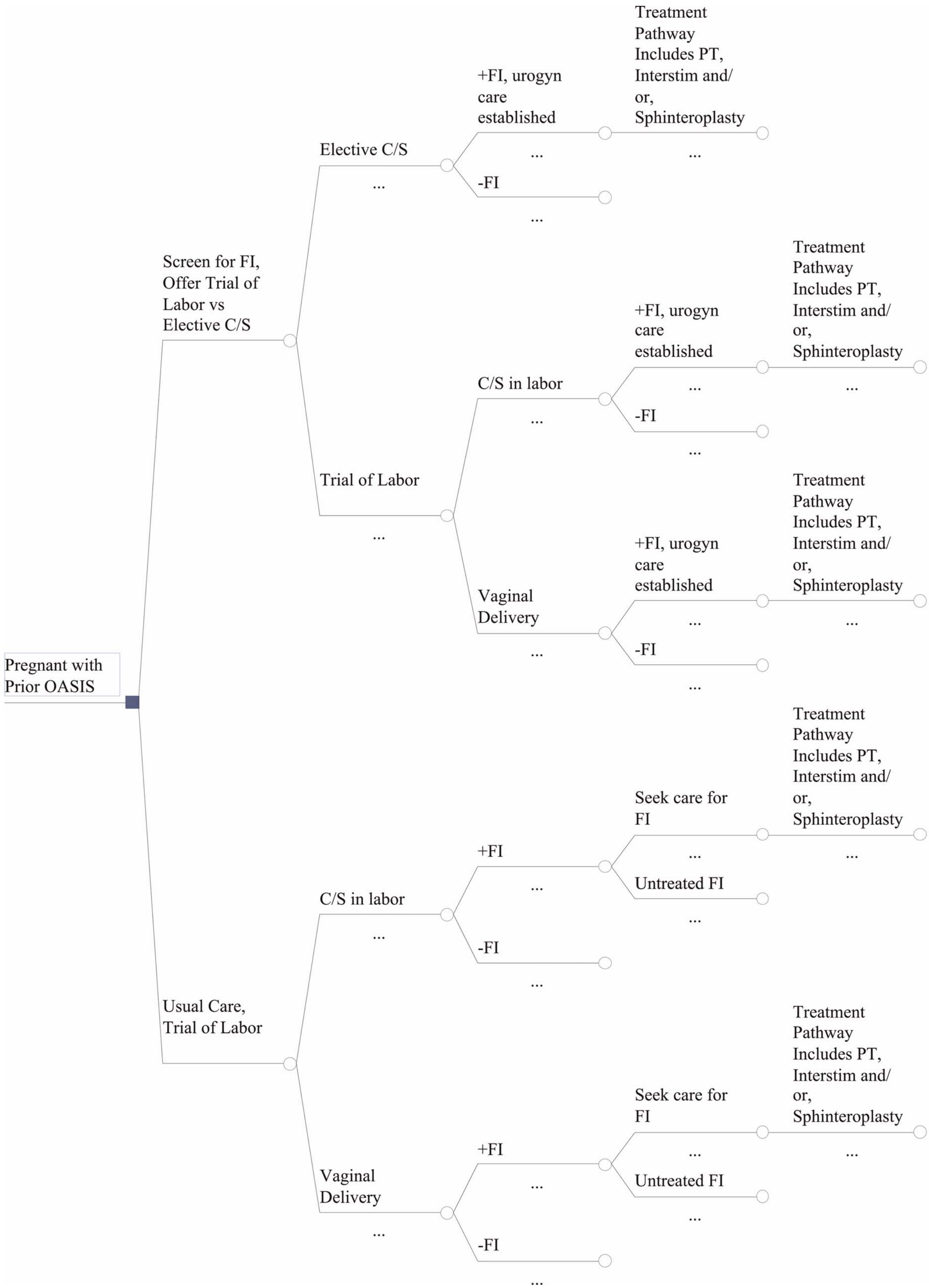

FIGURE 1. Simplified diagram of decision tree model, first subtree. The second subtree, modeling maternal peripartum complications, and the third subtree, modeling FI treatment, are not pictured in full because of space constraints, but the TreeAge file is available from the authors upon request. C/S, cesarean birth; FI, fecal incontinence; OASIS, obstetric anal sphincter injury; PT, physical therapy.

TABLE 1. Model Outcome Probabilities

Variable	Weighted Average Base-Case Model Probability	Range of Data From Sources	Source
Maternal morbidity with VD			
Death	0.0000211	0.000017–0.000082	13–16
Transfusion	0.00246	0.0011–0.0164	13,17–22
VTE (DVT, PE)	0.000307	0.000423–0.0008	13,17,19,23
Bladder injury	0.0032	N/A	21
Uterine injury	0.000664	0.000289–0.004	21,23
Infection (wound infection, endometritis)	0.00844	0.00478–0.0094	17–19,22
Hysterectomy	0.000305	0.0002–0.000422	13,23–25
Maternal morbidity with ECD			
Death	0.0000449	0–0.000059	13,15
Transfusion	0.0146	0.000235–0.0341	13,14,17–22
VTE (DVT, PE)	0.00162	0.000657–0.00319	17,19,23,26
Bladder injury	0.0025	N/A	21
Uterine injury	0.000634	0.0006–0.000646	21,23
Infection (wound infection, endometritis)	0.0413	0.0137–0.0457	17–19,22,26
Hysterectomy	0.00323	0.000834–0.00172	13,23,26
Maternal morbidity with CD in labor			
Death	0.000182	N/A	15
Transfusion	0.0173	0.0037–0.0312	17–20,22
VTE (DVT, PE)	0.00386	0.001–0.0045	17,19,23
Bladder injury	0.0025	N/A	Assumption–same as ECD
Uterine injury	0.00380	N/A	23
Infection (wound infection, endometritis)	0.044	0.0183–0.0847	17–19,22
Hysterectomy	0.00275	N/A	23
(+) FI after OASIS in 1st delivery	0.134	0.105–0.14	27,28
Select ECD	0.47	N/A	10
(–) FI after OASIS in 1st delivery			
Select ECD	0.222	N/A	10
TOL after one prior VD			
Successful VD	0.973	0.935–0.975	10,29,30
Develop new FI after 2nd delivery			
If 2nd delivery VD	0.142	0.106–0.254	10,31,32
If 2nd delivery ECD	0	N/A	Assumption
If 2nd delivery CD	0	N/A	Assumption
Seek medical care for FI	0.337	0.309–0.375	33,34
Conservative tx effective	0.781	N/A	35
Continue to 2nd-line treatment if conservative tx no effective	0.8	N/A	Assumption based on Brosa et al[36]
SNM is first 2nd-line tx (as opposed to sphincteroplasty)	0.5	N/A	Assumption
SNM responders	0.724	0.638–0.867	37–39
SNM effective	0.835	0.712–0.957	37,38,40,41
Sphincteroplasty effective	0.702	0.645–0.788	42–44
SNM failed, continue to 3rd-line tx	0.8	N/A	36
Sphincteroplasty failed, continue to 3rd-line tx	0.8	N/A	36

CD, cesarean delivery; DVT, deep vein thrombosis; ECD, elective cesarean delivery; FI, fecal incontinence; N/A, not applicable; OASIS, obstetric anal sphincter injury; PE, pulmonary embolism; SNM, sacral neuromodulation; TOL, trial of labor; tx, treatment; VD, vaginal delivery; VTE, venous thromboembolism.

TABLE 2. Model Utility Values

Variable	Utility Value	Source
Obstetric events		
Vaginal delivery	0.9972	45
Elective cesarean delivery	0.95	45
Cesarean delivery in labor	0.95	45
Maternal morbidity		
Death	0	
Transfusion	0.96	45
VTE	0.884	45
Surgical injury	0.76	45
Infection (wound infection, endometritis)	0.825	45
Hysterectomy	0.71	45
Anal incontinence		
"No FI" state	0.74	46
Disutility associated with FI	0.19	46
FI	0.55	46
FI treatment utilities		
SNM stage 1	0.91	47
SNM stage 2	0.915	47
SNM explant	0.775	47
Sphincteroplasty	0.87	45
PT/Meds for FI	0.87	Assumption

FI, fecal incontinence; PT, physical therapy; SNM, sacral neuromodulation; VTE, venous thromboembolism.

were obtained either from published literature or from the Tufts Medical Center Cost-Effectiveness Analysis Registry, which is a repository of published studies on utility values (Table 2). Utility scores range from 0 to 1, with 1 representing perfect health. These values were multiplied by the length of time spent in the health state corresponding to that utility, summed over time to calculate QALYs, which were the ultimate measure of effectiveness.

We used a 1-year time horizon, which began with the subsequent pregnancy and delivery. This was the shortest time that would allow for inclusion of all major events of interest: evaluation by a urogynecologist during the pregnancy, identification of persistent FI beyond the immediate postpartum period (6–12 weeks), diagnosis of FI and trial of first-line treatment, and escalation to subsequent treatment (6- to 12-week trial for each). We decided to exclude long-term analyses beyond this because the benefits of treatment for FI would be largely accrued by 1 year. After 1 year, there would be fewer additional interventions, and continuing beyond this point risked diluting the effects of the interventions in that first year. Thus, 1 year allowed the best window to assess the difference between the 2 management strategies. As such, no discount rate was needed.

We used the cost perspective of a third-party payer. Costs were gathered from the Medicare physician fee schedule reimbursement data or published literature and are shown in Table 3. Costs obtained from the medical literature were converted to 2019 U.S. dollars via consumer price index tables with year-specific currency conversion rates to account for inflation.

Our primary outcome of cost-effectiveness was determined by using the incremental cost-effectiveness

TABLE 3. Model Cost Estimates

Variable	Cost (2019 USD)	Source
Obstetric care		
Vaginal delivery	$4,357.35	48
Elective cesarean delivery	$5,861.38	48
Cesarean delivery in labor	$8,062.34	48
Obstetric complications		
Death	$0.00	
Transfusion	$15,104.16	49
VTE	$29,325.12	49
Surgical injury	$20,195.03	49
Infection	$12,666.03	50
Hysterectomy	$33,566.03	49
Fecal incontinence treatment		
Urogynecology referral (*CPT* code 99204)	$166.86	51
Follow-up office visits	$75.32	51
Conservative treatment		
Physical therapy (6 visits with *CPT* codes 90911 and 97032)	$624.96	51
Medication (imodium 2 tablets/d)	$0.76/d (2 mo for failed treatment, 12 mo for successful treatment)	52
Sphincteroplasty		
Sphincteroplasty procedure	$9,739.67	48
Endoanal ultrasound	$130.46	51
Anorectal manometry	$246.86	51
SNM		
1st-stage lead placement	$6,809.58	53
2nd-stage generator placement (including device cost)	$13,428.68	53
Follow-up office visits	$178.26	54
Surgical revision	$5,238.14	53
Surgical removal	$1,422.63	53
Diapers, absorbent materials, cost for 1 y	$298.33	48

CPT, *Current Procedural Terminology*, SNM, sacral neuromodulation; USD, U.S. dollars; VTE, venous thromboembolism.

ratio (ICER). Incremental cost-effectiveness ratios were calculated by first ranking strategies by increasing cost and then calculating ΔCost/ΔEffectiveness for adjacent strategies. The willingness-to-pay (WTP) threshold was set a priori at $50,000 per QALY. Strategies were considered "dominated' if they were both less effective and more expensive than another strategy. No ICER was reported for dominated strategies because they are not cost-effective.

Model robustness was assessed using multiple 1-way sensitivity analyses. For every model input variable, we reran the model in multiple iterations changing the input variable across its plausible range to determine whether there is a threshold in which the model outcome would be changed. This determines what would happen if our base case assignments for the model variables were incorrect and how this would affect model outcomes. For all probabilities, we assessed the entire possible range of 0% to 100%. For all costs, we assessed the range from 50% to 200% of the baseline costs.

RESULTS

Our model demonstrated that for pregnant patients with prior OASIS, UUC was cost-effective. Compared with the "usual care" strategy, the ICER for this strategy was $19,858.32 per QALY (Table 4). This was well below our WTP threshold of $50,000 per QALY. Costs increased by $1,080.88, which was a 21.0% increase over baseline. Effectiveness (QALYs) increased by 0.0544, a 5.96% improvement over baseline. Despite the increase in costs outpacing the increases in effectiveness, UUC was a cost-effective option.

Furthermore, our analysis showed that UUC reduced the ultimate rate of FI from 25.33% to 22.67%. It reduced the ultimate rate of patients living with untreated FI from 17.36% to 1.49%. The UUC strategy increased the rate of first-line FI treatment from 8.53% to 22.67%. The utilization of second-line FI treatment (SNM or sphincteroplasty) was affected less than first-line treatment and only increased from 1.49% to 3.97%. This is due to improved patient retention and increased access to treatment coupled with the high success rates of first-line treatment. Likewise, the rate of third-line treatment (ie, both SNM and sphincteroplasty, in succession but in either order) increased even less from 0.35% to 0.92%.

Universal urogynecologic consultation in women with prior OASIS did have other consequences. This strategy reduced the rate of vaginal delivery in a population with a prior successful vaginal delivery from 97.26% to 72.42%. An increase in cesarean births led to a 1.15% increase in the rate of peripartum maternal complications.

DISCUSSION

We demonstrated that, in a population of women with prior OASIS presenting with a subsequent pregnancy, UUC is a cost-effective intervention. It reduces both the rate of FI and the number of women who ultimately go untreated for this pathology. This is largely mediated through increased usage of first-line pharmacological and physical therapy modalities, with more modest increases in utilization of surgical interventions such as SNM and sphincteroplasty. Although the cesarean birth rate increases along with a minimal increase in peripartum complications, these deficits of the strategy are incorporated into the model, which results in the overall improvement in quality of life. Although some would argue whether $50,000 or $100,000 (or even higher) should be used as the WTP threshold for 1 additional QALY, our model showed that, in women with prior OASIS, UUC is well below even the most conservative thresholds. We therefore recommend implementing the strategy of UUC in this small but significant subpopulation of pregnant women.

Sensitivity analyses demonstrated few thresholds where changes in our input variables would change model outcomes. Universal urogynecologic consultation is no longer cost-effective if 75% of patients are ultimately referred to urogynecology in the "usual care" strategy. It is dominated by "usual care," meaning that routine screening is both more expensive and less effective once this variable reaches 88%. However,

TABLE 4. Cost, Effectiveness, and Incremental Cost-Effectiveness Ratio of UUC After OASIS

Strategy	Cost	Incremental Cost	Effectiveness (QALY)	Incremental Effectivenss (QALY)	ICER (2019 USD/QALY)
Usual care	$5,153.47	–	0.9132	–	–
Universal screening for FI	$6,234.35	$1,080.88	0.9676	0.0544	$19,858.32

FI, fecal incontinence; ICER, incremental cost-effectiveness ratio; OASIS, obstetric anal sphincter injury; QALY, quality-adjusted life-year; UUC, universal urogynecologic consultation; USD, U.S. dollars.

Simply Stated

Fecal incontinence (FI) is the involuntary leakage of solid or liquid stool from the rectum. It can develop as a result of trauma that occurs to the muscles, ligaments, and other structures of the pelvis (the "pelvic floor") during childbirth. When women experience trauma to the pelvic floor during childbirth, it is unclear how best to treat them during their next pregnancy. In this study, we performed a cost-effectiveness analysis using a decision tree model to determine whether it would be cost-effective for all of these patients to see a urogynecologist, a pelvic floor specialist, during their next pregnancy. We looked at factors such as the mode of delivery, complications related to childbirth, and treatment options for FI. Our model demonstrated that universal urogynecologic consultation is a cost-effective strategy. It decreases the rate of women who have FI, decreases the rate of women who live with untreated FI, and only marginally increases risks associated with childbirth.

these thresholds are both unlikely because Tetzschner et al[33] and Wagenius and Laurin[34] suggest that currently only 33.7% will seek medical care for FI in the current paradigm of "usual care" where screening and referral are not universal. In multiple 1-way sensitivity analyses, no other reasonable thresholds were identified. This speaks to model robustness and lends stronger validity to the outcomes of our model.

The optimal management of pregnant patients with OASIS in a prior delivery is a controversial subject and one that is difficult to study with conventional clinical trials. This situation lends itself to cost-effectiveness modeling. Population-based retrospective studies have reported that the rate of recurrent OASIS in these patients ranges from 3% to 13%. Some studies report that this risk is not significantly different from the general population[55,56] whereas others report up to a 5-fold increase in risk.[57,58] Furthermore, although studies have shown that subsequent vaginal deliveries increase the long-term risk and severity of FI,[10,31,32,59] it has not been proved that ECD completely mitigates this risk.[10] The pathophysiology of FI is complex, and our simplified model does not account for the development of FI unrelated to obstetric trauma. Nonetheless, these other risk factors are probably equally likely with or without a strategy of UUC and thus would not affect our results. It is well established that OASIS is a significant risk factor for FI, and it is important to understand how best to screen high-risk patients, both at the individual and health care system levels.

In a study published in 2003, McKenna et al[12] developed a decision model in which all women with prior OASIS had ECD with their subsequent pregnancies. Their model demonstrated that 2.3 ECDs are needed to prevent 1 case of anal incontinence and that the relative risk for maternal death from ECD is 2.6. They concluded that the increased risk of maternal mortality may be justified by the significant decrease in the risk of anal incontinence. It is worth noting that anal incontinence includes patients who have isolated incontinence of flatus and is far more common than FI (prevalence 39% vs 14%, respectively) in women with prior OASIS.[27] We chose FI as our outcome of interest because it is less likely that women would seek treatment for incontinence of flatus only. Furthermore, most studies assessing the eficacy of sphincteroplasty and SNM did not include patients with incontinence of flatus only.[37–41]

Cost-effectiveness studies have compared different treatment modalities for FI, but no study has determined if UUC of this high-risk group of pregnant women with prior OASIS is cost-effective. We showed that screening not only decreases the ultimate disease burden, it also increases utilization of treatment in symptomatic patients. Most of this effect is mediated by the increased utilization of noninvasive first-line treatment rather than surgical treatments.

A difficulty inherent to all cost-effectiveness models is the inability to account for all possible contingencies. For example, we did not account for the management of subsequent pregnancies beyond the second pregnancy. One decision analysis showed that ECD resulted in a 0.3% increased risk of maternal morbidity compared with trial of labor. This risk increased with each subsequent pregnancy up to nearly a 10% cumulative risk of maternal morbidity by the fourth CD.[60] Women desiring 3 or more children should be counseled on the risks of multiple cesarean deliveries as part of the decision-making process. Another limitation of our model is that we did not consider the differential fetal and neonatal morbidity based on mode of delivery. Furthermore, the pathophysiology of FI is complex and multifactorial. Our simplified model with its short time horizon cannot account for all of the variables that contribute to the development of FI.

In our model, we assumed that all patients would have access to a urogynecologist for assessment and treatment of FI as well as counseling on the impact of mode of delivery. Access to subspecialty care may be limited in certain geographical areas and may lead to delay or inability to seek care. Initial screening and treatment can certainly be offered by general obstetrician-gynecologists and primary care providers. However, available literature demonstrates that care seeking is currently low with "usual care" and that many generalists feel uncomfortable treating FI.[33,34,61] Moreover, for anything beyond initial screening and first-line treatment, referral to a subspecialist is likely needed. For these reasons, for the purposes of this study, we decided to incorporate universal referral to urogynecology.

In conclusion, our study showed that UUC and screening for FI in women with a prior history of OASIS are cost-effective strategies that decrease the overall incidence of FI and reduces the percentage of women with FI whose problems go untreated. Although it substantially increased the cesarean birth rate, it only marginally increases the risk of maternal morbidity with a net improvement in quality of life. We support incorporating this into routine obstetric practice.

ARTICLE INFORMATION

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