

A Cost-Effectiveness Analysis of Intrauterine Spacers Used to Prevent the Formation of Intrauterine Adhesions Following Endometrial Cavity Surgery

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INTRODUCTION

- Surgical procedures involving the endometrial cavity can damage the basal layers of the endothelial linings, leading to scar formation, including the development of endocervical and/or intrauterine adhesions (IUAs).¹⁻³
- IUAs are a major contributor to pregnancy loss, infertility, and pregnancy-related complications.⁴
- Preventing IUAs is an ideal treatment strategy. Various conforming spacers have been used following surgical procedures to prevent the occurrence and recurrence of IUAs.

OBJECTIVE

- The objective of this analysis was to estimate the cost-effectiveness of conforming spacers if used within the US healthcare system. Outcomes of interest include the number of events experienced and the costs associated with IUA formation.
- This analysis was designed to aid healthcare payers' and providers' decisions regarding the reimbursement for conforming spacers. Additionally, the model evaluates the potential clinical benefit of using intrauterine spacers.

METHODS

- To capture the health outcomes for patients, we utilized a decision tree model framework (Figure 2) that evaluates patients who receive procedures with a conforming spacer intervention and patients who receive procedures without a spacer.
- The analysis was conducted from a US payer perspective over a simulated three-and-a-half-year timeframe. Only direct healthcare costs associated with IUA treatment were considered.
- Model outcomes were calculated for the intervention and the comparator arms. The intervention arm included patients undergoing transcervical procedures receiving adjuvant treatment with an intrauterine spacer following surgery. In contrast, patients within the comparator arm were modeled to undergo transcervical procedures without adjuvant therapy.
- The model was first run using base case settings, and alternate settings were explored via scenario and sensitivity analysis. In alignment with the US payer perspective, the model considered direct healthcare costs.

KEY ASSUMPTIONS

- Following a primary procedure, all patients who develop clinically significant IUAs will experience infertility, which will lead them to undergo diagnostic procedures to determine whether IUAs are present. Patients who do not develop IUAs will not undergo diagnosis.
- All IUAs resulting from primary procedures are successfully identified through diagnostic procedures and treated using hysteroscopic lysis of adhesions (LOA). Patients with IUAs will not seek pregnancy until these are successfully removed.
- The efficacy of conforming spacers is like that of other barrier adjuvant treatments (hyaluronic acid gels) in terms of preventing the formation of IUAs and improving pregnancy outcomes.
- The model assumes equal randomization at each decision node. This assumption allows patients who would or would not receive conforming intrauterine spacers after the primary procedure to have a chance of receiving them following the secondary procedure.

Figure 1. Conceptualized genesis and prevention of intrauterine adhesions following hysteroscopic multiple myomectomy

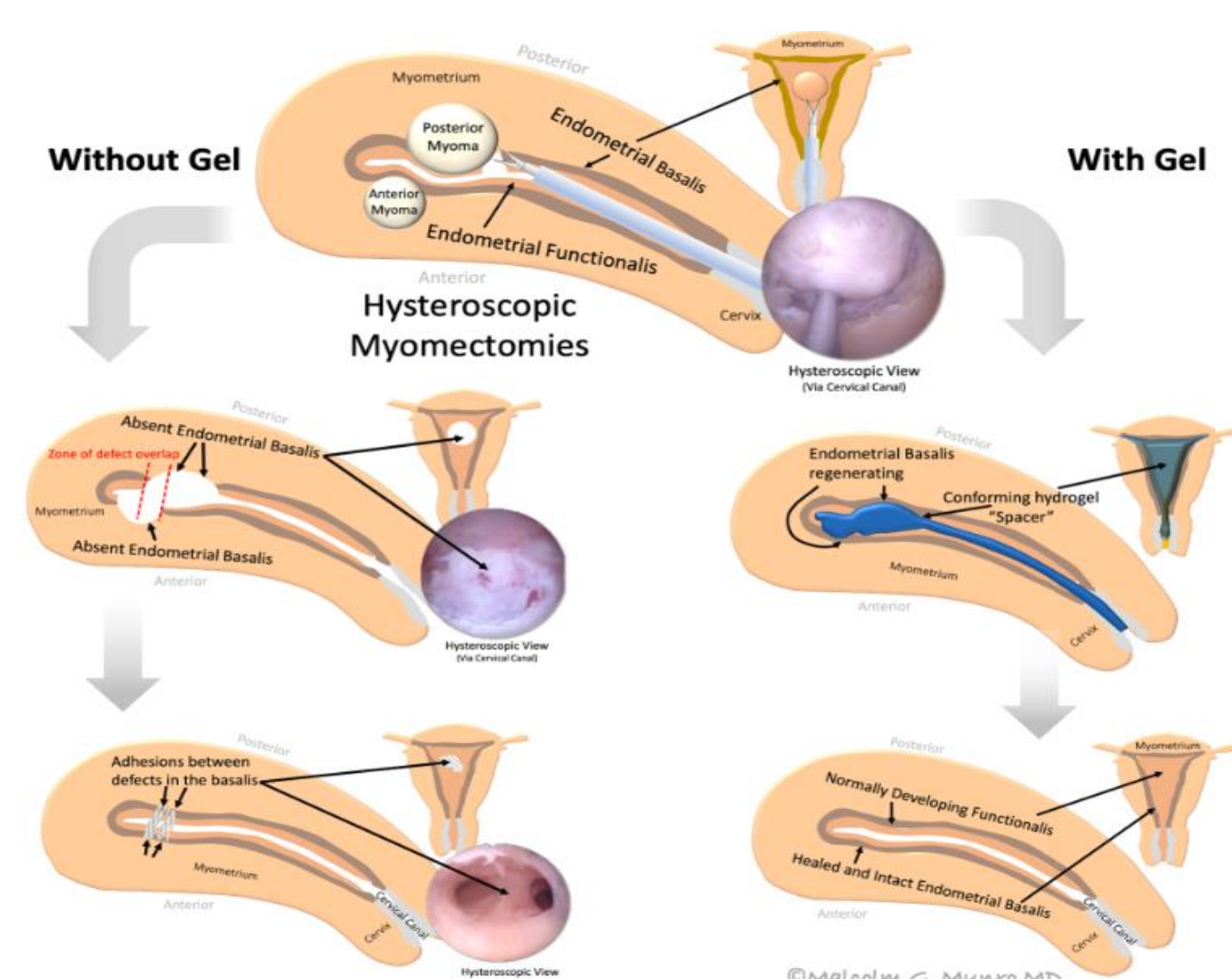
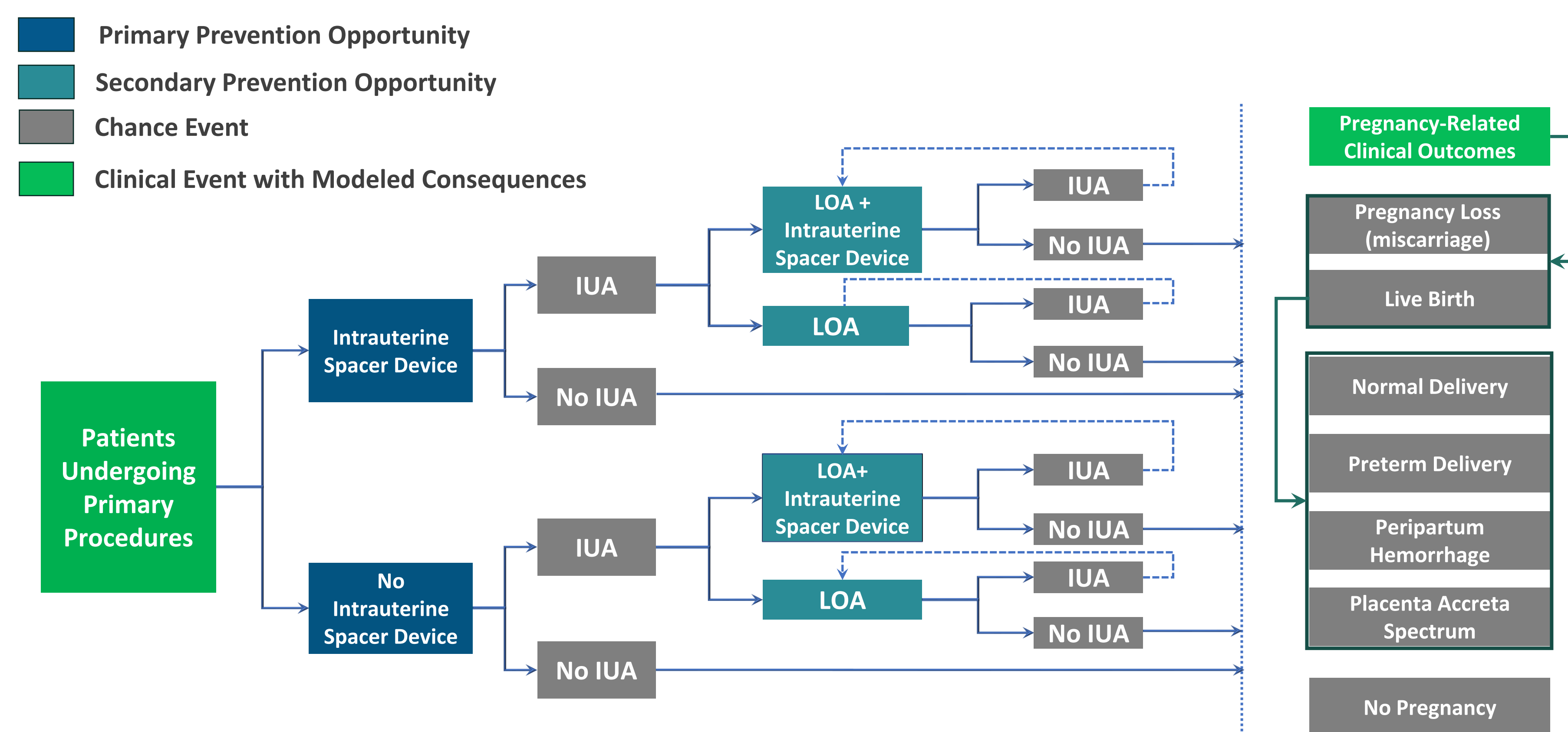


FIGURE 2. DECISION TREE MODEL FRAMEWORK



Abbreviations: IUA, intrauterine adhesion; LOA, lysis of adhesions

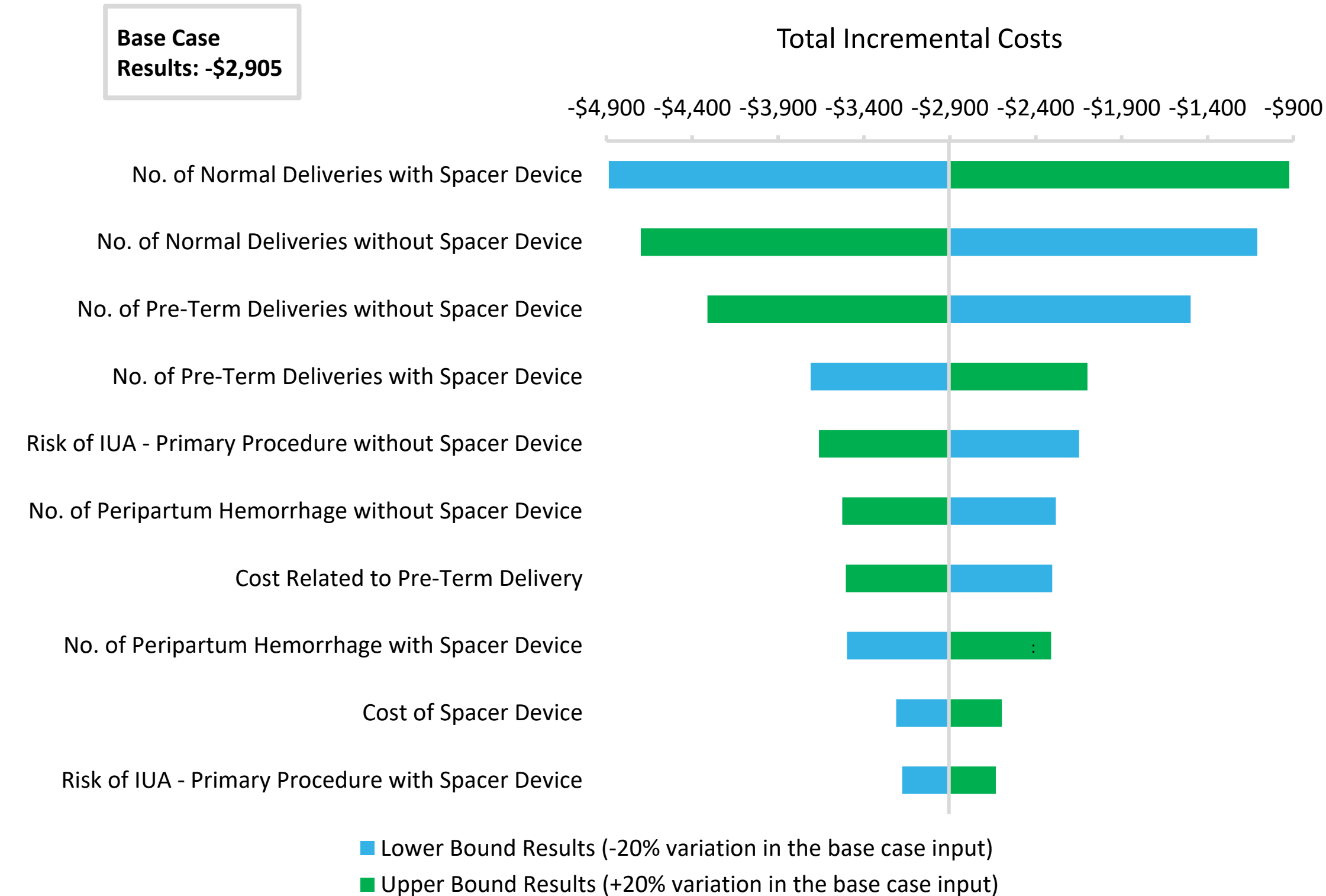
TABLE 1. BASE CASE RESULTS – PRIMARY POPULATION

Outcomes per Patient	Number of Events per 1,000 Patients			Costs per Patient		
	Transcervical Procedures + Intrauterine Spacer Devices	Transcervical Procedures (Comparator)	Incremental	Transcervical Procedures + Intrauterine Spacer Device	Transcervical Procedures (Comparator)	Incremental
Intrauterine Spacers Device	-	-	-	\$1,947	\$408	\$1,539
Procedure (LOA)	-	-	-	\$728	\$2,023	-\$1,295
Diagnostic (IUA discovery & confirmation of removal)	-	-	-	\$488	\$1,355	-\$867
Pregnancy-Related Events⁵						
Pregnancy Losses (miscarriage)	209	375	-166	\$147	\$264	-\$117
Placenta-accreta spectrum	65	60	4	\$670	\$625	\$45
Pre-Term Deliveries	45	78	-33	\$4,031	\$7,033	-\$3,002
Peripartum hemorrhages	104	109	-5	\$2,971	\$3,110	-\$139
Normal Deliveries	776	703	73	\$9,903	\$8,971	\$931
Pregnancy-related costs (total)	-	-	-	\$17,722	\$20,003	-\$2,282
Live births (total)	821	781	40	-	-	-
Total Costs	-	-	-	\$20,885	\$23,790	-\$2,905

TABLE 2. SCENARIO ANALYSES

Scenario	Model Results by Cost of Intrauterine Spacer Device				
	\$1,200	\$1,500	\$1,800 (Base case)	\$2,100	\$2,400
Base case (42 months)	-\$3,418	-\$3,162	-\$2,905	-\$2,649	-\$2,392
Short time horizon (6 months)	-\$1,218	-\$961	-\$705	-\$449	-\$192
Secondary prevention — (equal efficacy to primary prevention)	-\$2,254	-\$1,973	-\$1,691	-\$1,409	-\$1,128
Secondary prevention — (equal efficacy across the treatment arms)	\$27	\$309	\$590	\$872	\$1,154
Preterm delivery cost alternative	-\$2,174	-\$1,918	-\$1,662	-\$1,405	-\$1,149
High proportion of miscarriage surgery	-\$3,510	-\$3,253	-\$2,997	-\$2,740	-\$2,484
Inconsistent insurance coverage of newborns	-\$3,155	\$2,899	-9,642	-\$2,386	-\$2,129

Figure 3. ONE-WAY SENSITIVITY ANALYSIS



RESULTS

- Following intrauterine procedures, patients modeled to have an intrauterine spacer positioned had substantially fewer miscarriages (166 fewer per 1000 patients) and certain pregnancy-related complications (5 and 33 fewer for peripartum hemorrhage and preterm delivery, respectively).
- Intrauterine spacers in the primary prevention population resulted in an overall cost savings of \$2,905 per patient.
- We found that the total incremental cost savings from the routine use of conforming intrauterine spacers ranged from \$4,886 to \$925, within the range of sensitivity analyses conducted. This is presented as a tornado diagram in Figure 3.
- The most influential parameters impacting the model results include the number of normal deliveries with and without intrauterine spacers, the number of preterm deliveries, and the risk of IUA occurrence post-transcervical procedures without the use of space.
- Across the scenarios and tested unit costs:
 - Results tend to favor conforming spacers, with incremental costs ranging from -\$3,510 to \$1,154.
 - Only one scenario analysis yielded positive incremental cost results, wherein secondary prevention was analyzed with the assumption of equal efficacy across the treatment arms.
 - In that scenario, total incremental costs (\$590) were lower than those of the intrauterine spacer (\$1,800), demonstrating a partial offset of the spacer's cost.

CONCLUSIONS

- The model results presented herein suggest that the routine use of conforming intrauterine spacers following at-risk intrauterine procedures would be associated with an overall cost savings of \$2,905 per patient.
- These findings were robust to variations applied through one-way sensitivity analysis and several scenario analyses.
- Overall, conforming intrauterine spacers are likely to be a cost-effective option to prevent IUA formation, prepare for conception, and subsequently enable healthy pregnancy-related outcomes.
- The results from cost-effectiveness analyses were extrapolated at a national level using a budget impact analysis. The analysis revealed that use of gel spacers translates into cost savings of approximately \$20 million over a 5-year time horizon.

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DISCLOSURES

- DS, CM, AKJ, LS, WCL, and JK are employees of Atria.
- MGM and IF are consultants for Rejoni Inc.
- This study was fully funded by Rejoni Inc.

POSTER PRESENTED AT

ISPOR US, Atlanta, Georgia, USA; 5 May – 8 May 2024.

