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What to Expect When Expecting — With IBD

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Guest Contributor

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STRUCTURED ABSTRACT

Question: How can healthcare providers manage pregnant patients with inflammatory bowel disease (IBD)? How can they counsel patients seeking pregnancy and postpartum care?

Design: The Helmsley PIANO Expert Global Consensus group used GRADE[1] methodology to assess the quality of evidence and formulate recommendations when the evidence is available. For topics lacking data suitable for GRADE, the RAND/UCLA[2] appropriateness method was applied to achieve expert consensus. The population, intervention, comparison, outcome (PICO) format was used. The consensus panel included 39 international experts including gastroenterologists, colorectal surgeons, maternal-fetal medicine specialists, teratologists, and lactation experts.

Patients: Women with IBD before conception, during pregnancy, and in the postpartum period. There is also guidance on vaccine schedules for infants born to

mothers with IBD.

Interventions/Exposure: Ten topics are highlighted in this document: maternal factors impacting pregnancy, fertility, preconception counseling and optimization, management of active disease during pregnancy, management of pregnancy, use of IBD medications during pregnancy, use of IBD medications during lactation, pregnancy adverse events, fetal and neonatal adverse events, and vaccines.

Specific medications were discussed including 5-aminosalicylates, sulfasalazine, corticosteroids, methotrexate, thiopurines, anti-tumor necrosis factor agents, biosimilars, vedolizumab, ustekinumab, IL-23 agents, antibiotics, calcineurin inhibitors, sphingosine-1-phosphate receptor modulators, and Janus kinase inhibitors.

Outcomes: Outcomes discussed included pregnancy adverse events (low birth weight, preterm birth, congenital malformations, spontaneous abortion, and venous thromboembolism), mode of delivery, fetal and neonatal adverse events (neonatal intensive care unit admission, hospitalizations, childhood malignancy, developmental delay, and long-term health outcomes).

Data Analysis: Recommendations were graded as "strong" or "conditional" using the GRADE methodology. With a strong recommendation, providers should recommend the intervention for most patients. A strong recommendation is usually accompanied by High or Moderate Level of Evidence from well-designed randomized controlled trials (RCTs) or RCTs with mild methodologic limitations. With a conditional recommendation, providers might suggest this therapy or diagnostic test, while other providers would not suggest this intervention in similar patients. Conditional recommendations are usually accompanied by Low quality or Very Low quality of evidence from studies without a comparator arm or placebo for comparison. The RAND panel was applied where robust evidence was lacking.

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Results: There are 34 recommendations and 35 consensus statements (***Tables 1 and 2***). Topics covered include fertility, management of disease during pregnancy, medications in pregnancy, and fetal and neonatal adverse events.

TABLE 1. GRADE Statements		Recommendation	Level of evidence
Maternal factors impacting pregnancy to be addressed in counseling			
1	We suggest counseling that children with first-degree relatives with IBD, as compared with those without, have an increased risk of development of IBD.	Conditional	Low
Fertility			
2	We suggest counseling that women with IBD may have decreased fertility compared with women without IBD.	Conditional	Very low
3	In women with ulcerative colitis, we suggest counseling that prior ileal pouch anal anastomosis is associated with decreased fertility when compared with women with ulcerative colitis who have not had ileal pouch anal anastomosis.	Conditional	Very low
4	In women with IBD, we recommend counseling that active disease increases the risk of infertility as compared with inactive disease.	Strong	Very low
5	We suggest counseling that women with IBD may have comparable effectiveness of assisted reproductive technology when compared with women without IBD as measured by live birth.	Conditional	Very low
6	We suggest counseling that women with IBD who have undergone pelvic surgery with IBD have similar effectiveness of in vitro fertilization when compared with women without IBD, as measured by live birth.	Conditional	Very low
Preconceptional counseling and optimization			
7	We recommend that women with IBD undergo preconceptional counseling.	Strong	Low
Management of disease activity during pregnancy			
8	We suggest that urgent and emergent IBD surgery during pregnancy be completed when required, and not based on trimester.	Conditional	Very low
Management of pregnancy			
9	We suggest that pregnant women with IBD take low-dose aspirin by 12–16 weeks gestation to prevent preterm preeclampsia.	Conditional	Low
10	We suggest that pregnant women with Crohn's disease and active perianal disease undergo Cesarean delivery.	Conditional	Very low
11	We suggest that pregnant women with IBD and prior ileal pouch anal anastomosis consider Cesarean delivery.	Conditional	Very low
Medications in pregnancy			
12	For women with IBD who are pregnant or attempting conception, we recommend continuing maintenance 5-ASA therapy.	Strong	Low
13	In women with IBD who are pregnant or attempting conception, we suggest continuing maintenance sulfasalazine therapy.	Conditional	Very low
14	In women with IBD who are pregnant, we suggest use of corticosteroid therapy when clinically necessary with appropriate monitoring.	Conditional	Low
15	In women with IBD, we recommend discontinuing maintenance methotrexate therapy prior to conception.	Strong	Very low
16	In women with IBD who are pregnant or attempting conception, we suggest continuing maintenance thiopurine therapy as data does not demonstrate an increased risk of congenital malformations or infant infections.	Conditional	Very low
17	In women with IBD who are pregnant or attempting conception, we recommend continuing maintenance anti-TNF therapy throughout pregnancy.	Strong	Low
18	In women with IBD who are pregnant or attempting conception, we suggest continuing maintenance combination therapy with an anti-tumor necrosis factor and thiopurine therapy throughout pregnancy.	Conditional	Very low
19	In women with IBD who are pregnant or attempting conception, we suggest continuing maintenance vedolizumab therapy throughout pregnancy.	Conditional	Low

(*table continued on next page*)

Table 1 continued

	GRADE Statement	Recommendation	Level of evidence
20	In women with IBD who are pregnant or attempting conception, we suggest continuing maintenance ustekinumab therapy throughout pregnancy.	Conditional	Low
Medications during lactation			
21	We recommend breastfeeding as it is not associated with an increased risk of disease exacerbation in women with IBD.	Strong	Very low
22	We suggest counseling that infants born to mothers on anti-TNF therapy who breastfeed have no increased risk of infection in the first 12 months of life.	Conditional	Very low
Pregnancy adverse events			
23	We suggest counseling that women with IBD as compared with women without IBD have an increased risk of adverse pregnancy outcomes including low birth weight and preterm delivery.	Conditional	Very low
24	We suggest counseling that women with IBD with moderate to severe disease activity have an increased risk of spontaneous abortion as compared with women without IBD or women with mild IBD.	Conditional	Very low
25	We suggest counseling that pregnant women with IBD have an increased risk of VTE during pregnancy as compared with pregnant women without IBD.	Conditional	Low
26	We suggest counseling that pregnant women with IBD have an increased risk of VTE during the postpartum as compared with pregnant women without IBD.	Conditional	Low
Fetal and neonatal adverse events			
27	We suggest counseling that children born to women with IBD have an increased rate of neonatal intensive care unit admissions and hospitalizations in the first year of life compared with children born to women without IBD.	Conditional	Very low
28	We suggest counseling that children born to women with active IBD have an increased rate of small for gestational age and low birth weight compared with children born to women with inactive IBD.	Conditional	Very low
29	We suggest counseling that children born to women treated with anti-tumor necrosis factor therapy, ustekinumab, or vedolizumab during pregnancy have no increased risk for early childhood malignancy.	Conditional	Very low
30	We suggest counseling that children born to women treated with anti-tumor necrosis factor therapy, ustekinumab, or vedolizumab during pregnancy have no increased risk for early childhood developmental delay.	Conditional	Very low
31	We suggest counseling that children born to women treated with thiopurine therapy during pregnancy have no increased risk for early childhood developmental delay.	Conditional	Very low
Vaccines			
32	We recommend that inactive vaccines be provided to children born to mothers with IBD on anti-TNF agents.	Strong	Very low
33	We suggest that live rotavirus vaccine may be provided in children with in utero exposure to biologics.	Conditional	Very low
34	We recommend that live Bacillus Calmette-Guérin vaccine be avoided in the first 6 months[a] of life in children with in utero exposure to anti-TNF therapy due to risk of disseminated tuberculosis and associated mortality.	Strong	Very low

[a]Regional risk should be considered.

5-ASA, 5-aminosalicylate; IBD, inflammatory bowel disease; TNF, tumor necrosis factor; VTE, venous thromboembolism.

Table 2. Consensus statements	
Maternal factors impacting pregnancy	
1	Children born to a parent with Crohn's disease may have a higher risk of developing IBD than children born to a parent with UC.
Fertility	
2	Women with IBD may have reduced fertility compared with women without IBD due to reduced ovarian reserve.
3	Women with IBD may undergo oocyte retrieval without increased risk of flare.
Preconceptional counseling and optimization	
4	Women with IBD desiring contraception should use long-acting reversible contraception over estrogen-containing contraceptives.
5	Women with IBD should be in documented remission and medically optimized prior to elective conception.
Management of disease activity during pregnancy	
6	Endoscopy during pregnancy among women with IBD is low risk but should only be performed if it may change management.
7	If cross-sectional imaging is needed during pregnancy, intestinal ultrasound and MRI without gadolinium are preferred to CT.
8	Fecal calprotectin is useful for monitoring disease activity in pregnant women with IBD.
Management of pregnancy	
9	Pregnancies for women with IBD should be considered as high risk for complications.
10	Women with current or past history of rectovaginal fistulas should deliver by Cesarean delivery.
11	Women with IBD should be assessed early in pregnancy or preconception for nutritional status, weight gain, and micronutrient deficiency.
Medications during pregnancy	
12	Women with IBD who are pregnant and with active disease should start or optimize the same appropriate therapies as in non-pregnant patients, except for thiopurines, methotrexate, JAKis inhibitors, and S1P receptor modulators.
13	In women with IBD who continue thiopurines during pregnancy, precaution should be taken for intrahepatic cholestasis by measurement of liver enzymes, metabolite levels, and consideration of split dosing.
14	Women with IBD who are pregnant and have infections, fistula, or pouchitis that require antibiotics may take an appropriate course of a low-risk antibiotic.
15	Women with IBD may initiate or continue calcineurin inhibitors (cyclosporine and tacrolimus) during pregnancy with careful monitoring if there are no viable alternate treatment options available.
16	Women with IBD who are pregnant or attempting conception should continue biosimilars to existing biologics.
17	Women with IBD who are pregnant or attempting conception should continue anti-interleukin (IL)-23 therapy throughout pregnancy (mirikizumab, risankizumb, guselkumab).
18	Women with IBD should discontinue ozanimod at least 3 months prior to conception unless there is no effective alternative therapy to maintain maternal health.
19	Women with IBD should discontinue etrasimod at least 1–2 weeks prior to conception unless there is no effective alternative therapy to maintain maternal health.
20	Women with IBD should discontinue tofacitinib at least 4 weeks prior to conception unless there is no effective alternative therapy to maintain maternal health.
21	Women with IBD should discontinue upadacitinib at least 4 weeks prior to conception unless there is no effective alternative therapy to maintain maternal health.
22	Women with IBD should discontinue filgotinib at least 4 weeks prior to conception unless there is no effective alternative therapy to maintain maternal health.
Medications during lactation	
23	Mothers with IBD currently on 5-ASA/sulfasalazine may breastfeed.
24	Mothers with IBD currently on thiopurines may breastfeed.
25	Mothers with IBD currently on corticosteroids may breastfeed.
26	Mothers with IBD currently on anti-TNF agents (infliximab, adalimumab, golimumab, certolizumab) may breastfeed.
27	Mothers with IBD currently on anti-integrins (vedolizumab, natalizumab) may breastfeed.

(*table continuted on next page*)

Table 2 continued	
Consensus statements	
28	Mothers with IBD currently on anti-interleukin-12/23 and anti-interluekin-23 agents may breastfeed (ustekinumab, risankizumab, mirikizumab, guselkumab).
29	Mothers with IBD currently on biosimilars may breastfeed.
30	Mothers with IBD currently on S1P receptor modulators (etrasimod or ozanimod) should not breastfeed.
31	Mothers with IBD currently on JAKis (tofacitinib, upadacitinib, filgotinib) should not breastfeed.
Pregnancy adverse events	
32	Controlling disease activity during pregnancy among women with IBD is critical to reduce adverse outcomes.
Vaccines	
33	Inactive vaccines should be given on schedule to infants of women with IBD regardless of in utero IBD medication exposure.
34	Children exposed to JAKis or S1P receptor modulators in utero may receive live vaccines after 1 month of age.
35	Live vaccines can be given to infants of mothers breastfeeding while on biologics.

5-ASA, 5-aminosalicylate; CT, computed tomography; IBD, inflammatory bowel disease; JAKis, Janus kinase inhibitors; MRI, magnetic resonance imaging; S1P, sphingosine-1-phosphate; TNF, tumor necrosis factor.

COMMENTARY

Why Is This Important?

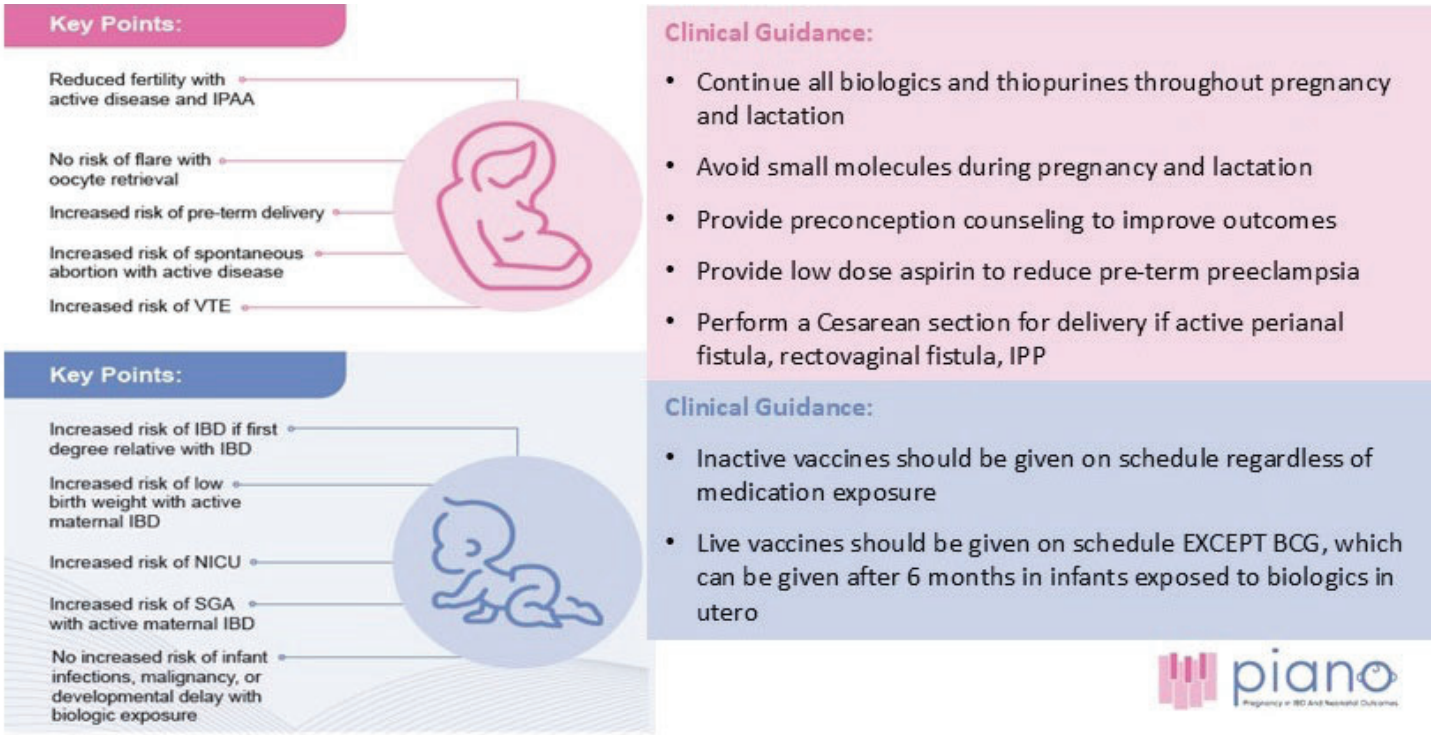
A significant portion of patients with IBD are of child-bearing age and many seek counseling on expectations for fertility, medication use during pregnancy, and pregnancy outcomes. While pregnant women are excluded from clinical trials, there are data from post-marketing registries, insurance databases, and national prospective registries like the Pregnancy in Inflammatory Bowel Disease and Neonatal Outcomes (PIANO) registry. This is the first consensus statement on IBD management during pregnancy. Prior publications on this topic, from the United States and Europe, were developed when fewer therapies and less robust safety data were available. Since then, the therapeutic landscape has expanded, with additional biologics and more real-world data supporting safety in pregnancy, lactation and the neonatal period.

Key Study Findings

The guidelines still emphasize the importance of preconception counseling and achieving disease remission prior to conception to lower the risk of adverse pregnancy outcomes. Decreased fertility remains an important outcome in post-surgical patients, especially in patients with ileal pouch anal anastomosis.

There are several new recommendations in this statement.

- A key change is that all biologics, including vedolizumab and IL-23 inhibitors, are now recommended to



Visual abstract: Global Consensus on the Management of Pregnancy in IBD.
BCG, Bacillus Calmette-Guerin; IBD, inflammatory bowel disease; IPAA, ileal pouch anal anastomosis; NICU, neonatal intensive care unit; SGA, small gestational age; VTE, venous thromboembolism.

be continued during pregnancy. Prior recommendations recommended continuing anti-TNF agents but were more cautious around newer agents.

- There is also a recommendation to initiate aspirin between gestational weeks 12 and 16 for pre-eclampsia prevention.
- Another new recommendation is that the live rotavirus vaccine can now be given on schedule even after in utero biologic exposure, and that live vaccines can be given after one month of age after in utero small molecule exposure. Use of small molecules remains cautioned during pregnancy and breastfeeding due to the ability to passively cross the placenta in the first trimester when organogenesis occurs.

Caution

The major limitation is comparative and prospective data on newer therapies, resulting in reliance on expert consensus for many recommendations.

My Practice

Our practice aligns with the new global consensus statement for the management of IBD during pregnancy. We discuss pregnancy planning with patients early when making new treatment decisions and recognize that many patients have contemplated the topic well before bringing it up in clinic. It is a source of apprehension for many patients, and we think the consensus statement provides reassurance that most of our treatment options are safe in pregnancy and breastfeeding. This is particularly

important given the protective role of breastfeeding in reducing the risk of IBD development in offspring.[3]

As an aside, we have also seen patients with prior anti-TNF non-response with severe disease for whom we induce remission with upadacitinib and then transition to a biologic for pregnancy planning. This requires a careful risk-benefit discussion and a recommendation to avoid conception until after the transition. Also, as the consensus statement notes, small molecules should not be withheld from who have no immediate plans for conception, if they represent the most appropriate therapy for their disease.

While obstetricians routinely prescribe aspirin for pre-eclampsia prevention in other populations, we have observed that some defer this decision to gastroenterologists due to concern for IBD exacerbation. We have now begun citing this consensus statement directly in interdisciplinary discussions to support consistent care.

For Future Research

Ongoing data from prospective registries such as PIANO will provide more information on pregnancy outcomes for advanced therapies, including oral biologics currently under investigation. We anticipate the results from ongoing studies, such as the MOMMY-IBD and MELODY trials, examining the impact of maternal diet in pregnancy on the infant microbiome as a potential modifiable factor in the risk of IBD development.[4]

Conflict of Interest

Drs. Chaudhary and Al Kazzi report no potential conflicts of interest related to this study.

Note: An author of this study are active on social media. Tag them to discuss their work and this EBGI summary.

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