# ORIGINAL ARTICLE



# Pregnancy outcomes after stoma surgery for inflammatory bowel disease: The results of a retrospective multicentre audit

# The PAPooSE Study Group\*

#### Funding information

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## Abstract

**Aim:** There is a paucity of data on pregnancies in women with stomas due to inflammatory bowel disease (IBD). The aim of this study was to assess stoma, IBD, obstetric and neonatal outcomes in pregnant patients with IBD and a stoma.

**Method:** Multicentre retrospective audit in 15 UK hospitals. Pregnancy, stoma and neonatal outcomes were elicited from routinely collected hospital records.

**Results:** Data on 82 pregnancies from 77 patients (mean age 31.4 years, 60.9% Crohn's disease, 35.4% ulcerative colitis, 3.6% IBD-U) were included. Stoma types included ileostomy in 72 (88%) and colostomy in 10 (12%) women. There was one reported miscarriage, one still birth and 80 live births. Delivery occurred in 58 cases by caesarean section (CS), of which 44 were performed electively and 14 as emergency CS. The overall CS rate was 73%. Premature delivery before week 37 occurred in 19% and birth weight <2,500 g in 17%. Significant stoma related complications occurred during 20 (24%) pregnancies and included stoma prolapse in nine cases (2 required surgery), parastomal hernias in three cases (2 required surgery) and small bowel obstructions in seven cases (3 required surgery).

**Conclusions:** Pregnancy for women who previously had stoma formation for IBD is associated with higher rates of caesarean section and stoma complications. Future prospective studies should capture data, including patient reported outcomes, to gather a full picture on the impact of pregnancy after stoma surgery for IBD.

#### KEYWORDS

IBD, Pregnancy, Stoma Surgery

# INTRODUCTION

Approximately 9,000 ileostomies, and 6,400 colostomies are performed each year in the UK [1,2]. While ileostomies or colostomies can be formed for many reasons, the most common are inflammatory bowel disease (IBD) and colorectal cancer. According to the latest epidemiological studies there are 500,000 people in the UK living with IBD, and the highest incidence is amongst those aged 20-29 [3]. This is the age at which patients often start to think about their future, including starting a family. Decision-making on having a family is a complex issue for young women with IBD incorporating choice of medications, impaired fertility, mode of delivery with

\*See Appendix 1 for all the members of The PAPooSE Study Group.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes. © 2022 The Authors. *Colorectal Disease* published by John Wiley & Sons Ltd on behalf of Association of Coloproctology of Great Britain and Ireland. potential impact on sphincter function, and stoma function due to pressure of the gravid uterus [4,5].

Recent research has shown that the birth rates for patients with IBD are significantly lower than in the general population [6]. This may reflect patients having to cope with the physical effects of IBD but is at least in part due to poor knowledge of pregnancy related issues in IBD which leads to high levels of fear and anxiety regarding pregnancy while also dealing with IBD [4,7,8]. It could therefore be anticipated that these concerns would persist following stoma formation for IBD, and even increase given the paucity of data on pregnancy and stoma function. We know that both active IBD and IBD surgery (especially approaches involving the pelvis) can have a negative impact on a patient's ability to conceive a pregnancy [6,9]. Anecdotal reports suggest that many patients with stomas are concerned about becoming pregnant, and the impact of pregnancy on their stoma function.

The existing literature has previously focused on fertility and conception but data on patient experience and outcome of pregnancy after stoma surgery are scarce [9,10]. The recent Association of Coloproctology of Great Britain and Ireland (ACPGBI) IBD surgery guidelines alluded to the limited literature (case reports) of the issues that can face pregnant IBD patients with a stoma but noted potential changes to stoma shape and function, difficulty in fitting stoma appliances, intestinal obstruction and parastomal hernia [11]. The joint IBD/Obstetric working group has also highlighted that pregnancy after stoma formation is a key area of concern requiring further research [12].

The aim of this study was to describe the management of women with stomas related to IBD during pregnancy. This included assessment of IBD outcomes, stoma outcomes, obstetric and neonatal outcomes in pregnancies of women who had stomas formed for IBD prior to the reported pregnancies.

# METHODS

This was conducted as a service evaluation, which allows teams to routinely collect data to assess how services are delivered without need for formal ethical approval, subject to standard data protection rules [13]. All sites were required to secure local audit and Caldicott Guardian permissions to collect data. The audit included centres from the joint IBD/Obstetric working group and recruited further centres via IBD Consultant networks to participate in the audit. This study is reported in line with STROBE guidance.

#### Participants

Female patients who had a confirmed diagnosis of IBD who had experienced pregnancy following stoma formation (ileostomy or colostomy) between 2014 and 2020 were included in the study. We excluded patients with stomas for reasons other than IBD and those who had their stoma reversed prior to pregnancy. Of 15 centres

#### What does this paper add to the literature?

This retrospective audit is the only comprehensive modern report of pregnancy outcomes following stoma surgery for inflammatory bowel disease. This paper highlights the need for patients to be counselled appropriately with regards to the method of delivery and the potential complications of pregnancy with a stoma.

taking part, there were 11 specialist University Teaching Hospitals and four District General Hospitals.

# **Data collection**

Items included in the data collection were agreed by the multidisciplinary study team with significant input from expert patients. Data on age, diagnosis, extent and behaviour of disease, type of stoma and details of previous surgery were collected. Disease activity during pregnancy and postpartum activity were recorded by physician global assessment (PGA) and reported as the worst disease activity during any trimester. Medication exposure during pregnancy was recorded for use of mesalazine, steroids, biologics and thiopurines. Data on whether conception was natural or assisted was collected, alongside data on week of delivery and delivery methods. Obstetric, IBD and serious stoma complications (herniation, prolapse, obstruction or need for further surgery on the stoma) within 30 days of delivery were also collected, as were data on stoma complications during pregnancy and whether surgical intervention was needed. Data was collected from local IBD-pregnancy databases and/or clinical charts.

Sites were required to submit pseudoanonymised data via the secure nhs.net email system and no raw patient data left the National Health Service.

#### **Outcomes and definitions**

The coprimary endpoints were stoma complications and obstetric mode of delivery. Further obstetric outcomes collected were week of gestation, birth weight, and congenital abnormalities. In accordance with national guidance premature delivery was defined as birth before 37 weeks of gestation and birth weight <2,500 g.

IBD outcomes collected were flares defined as need for changes in medical therapy, and high output from the stoma. These were reviewed and categorised by gastroenterology members of the research team.

Surgical outcomes collected were intestinal obstruction, stoma prolapse, stoma herniation, and need for further stoma surgery. Serious stoma complications were included as small bowel obstruction, stoma prolapse, peristomal fistulas, and parastomal hernias.



These were reviewed and categorised by surgical members of the research team.

## Patient and public involvement

This study was conceived following a research sandpit hosted by the Bowel Disease Research Foundation (now known as Bowel Research UK) on behalf of IA (Ileostomy and Internal Pouch Association) and the Kingston Trust. The Chief Investigator is a patient and the study steering group includes a patient representative who has personal experience of pregnancy after stoma surgery for IBD.

## Analysis

Demographic and disease characteristics were analysed by descriptive statistics. Pregnancy outcomes were presented on a per pregnancy rather than per patient basis unless otherwise specified. Comparative analysis used Fisher's exact test for categorical and Student's *t*-test for noncategorical data. The analysis was performed with SPSS 25 (IBM). Significance was set at 5% (p < 0.05). As an exploratory cohort study, no formal sample size calculation was performed.

## Role of the funding source

The study funders had no role in the study design, collection, analysis and interpretation of data, or in the writing of this manuscript.

# RESULTS

There were 82 pregnancies in 77 women with a mean age of 31.4 years (range 20–39 years, Table 1). Of these 50 (60.9%) had a diagnosis of Crohn's disease (CD), 29 (35.4%) ulcerative colitis (UC), and three (3.6%) IBD-unclassified (IBD-U). One woman was a current cigarette smoker, while 13 were previous smokers. Medical treatments included five treated with mesalazine, 17 with thiopurines and 29 on biologics. Biologics were stopped in 20 of 29 (69%) cases at a mean of 25 weeks' gestation. In 45 patients no medical therapy for IBD was required during pregnancy. Highest recorded IBD disease activity during pregnancy was remission in 48 (59%), mild in 11 (13%), moderate in 12 (15%) and severe in six (7%) cases (no data available for 5 cases).

Stoma types included lleostomy in 72 (88%) and colostomy in 10 (12%) pregnancies. Parastomal hernias were present in seven (8.5%) patients prior to pregnancy. The number of previous abdominal operations were one in 39 (51%), two in 22 (29%), three in 14 (18%), four in one (1%), and five in one case (1%; missing data in 5 cases). Active perianal CD was present in 10 patients (12%), while 18 (22%)

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#### TABLE 1 Cohort composition (all presented by pregnancies)

Characteristic		Percentage (%)		
Age (mean)	31.4 years (range 20–39 years)			
Smoking status				
Current	1	1		
Previous	13	16		
Never	68	83		
Diagnosis				
Crohn's disease	50	61		
Ulcerative colitis	29	35		
IBD-unclassified	3	4		
Ulcerative colitis/IBD-U phenotype				
E1	1	4		
E2	5	19		
E3	21	77		
Unknown	5			
Crohn's disease phenoty	ре			
L1	2	4		
L2	20	40		
L3	30	60		
L4	6	12		
B1	21	42		
B2	8	16		
B3	24	48		
Perianal disease	9	18		
Medication exposure du	ring pregnancy			
Mesalazine	5	6		
Thiopurine	17	21		
Biologics	29	35		
Type of stoma				
lleostomy	72	88		
Colostomy	10	12		

had a history of previous perianal CD. Table 2 sets out the main outcomes by type of IBD.

#### Obstetric mode of delivery

Of 80 pregnancies with a live infant born, 10 (12.5%) were normal vaginal deliveries and 10 (12.5%) were assisted (ventouse, forceps) vaginal deliveries. Perineal tears included one first degree tear and five second degree tears in 20 vaginal deliveries. Mode of delivery data was missing in two cases. Of 58 caesarean sections (CS), 44 (55% of all deliveries) were performed electively and 14 (17.5% of all deliveries) as emergency CS. The overall CS rate was 73%. In 19 elective CS, an IBD indication for CS was documented.

# TABLE 2 Outcomes by type of IBD (all presented by pregnancies)

Outcomes		Type of IBD		
Obstetric mode of delivery				
Vaginal delivery	10	UC: 7		
		CD: 3		
		IBDU: 0		
Assisted vaginal delivery	10	UC: 2		
		CD: 6		
		IBDU: 2		
C section	44	UC: 13		
		CD: 31		
		IBDU: 0		
Emergency C section	14	UC: 7		
		CD: 6		
		IBDU: 1		
Birth outcomes				
Birth weight < 2,500	13	UC: 6		
		CD: 6		
		IBDU: 1		
Delivery before 37 weeks	14	UC: 7		
		CD: 5		
		IBDU: 2		
Stoma complications				
Obstruction	9	UC: 6		
		CD: 2		
		IBDU: 1		
Prolapse	8	UC: 0		
		CD: 6		
		IBDU: 2		
Other	5	UC: 1		
		CD: 4		
		IBDU: 0		

## Stoma complications

In 20 (24%) pregnancies, serious stoma-related complications occurred. Prolapse of the stoma occurred in nine (11%) cases, of which two required an operation to correct the prolapse during pregnancy. New onset of parastomal hernia was reported in three (4%) pregnancies, of which two required surgical operative management during pregnancy. Small bowel obstruction occurred in seven (9%) cases. One of these was just proximal to the stoma and resolved with conservative management. Of six small bowel obstructions occurring at stoma level, three required surgical intervention during pregnancy, while the other three settled with conservative management. One patient developed peristomal enterocutaneous fistulas that were managed conservatively. All major stoma complications occurred in patients with ileostomies, while no major stoma complications occurred in patients with colostomies. Stoma complications were comparable between patients with CD and those with UC/IBD-U (20% vs. 34%; p = 0.19). There was no association between clinically active IBD during pregnancy and the occurrence of major stoma complications (p = 0.49). Minor complications included reactions to adhesives from stoma appliances and occurred in three cases.

## **Birth outcomes**

Of 82 pregnancies, 77 were naturally conceived and five were conceived using assisted fertility techniques. We recorded one miscarriage at 5 weeks and a still birth at 30 weeks' gestation.

There were 81 infants (1 twin pregnancy) born at mean gestation of 37 weeks (range 29–41 weeks) with delivery before week 37 occurring in 14 of 74 documented (19%) cases. Mean birth weight was 3,030 g (standard deviation 720 g) with weight <2,500 g at birth in 13 of 75 documented cases (17%). A single case of congenital malformation (undeveloped larynx, undescended testes) was recorded in a case exposed to biologic therapy.

## **Obstetric complications**

Postpartum haemorrhage occurred in six (7.5%) cases, of which one required surgical intervention. Bladder injuries during CS occurred in three patients. There were two cases of postpartum acute renal failure, two postoperative wound infection, and one postoperative collection requiring radiological drainage. During two CS deliveries, significant adhesions were encountered that required adhesiolysis.

#### Inflammatory bowel disease complications

Complications relating to IBD occurred in 11 cases (13%). These included two flares requiring change of medical treatment, one case of a high output stoma, one of perianal sepsis and one with subacute obstruction after emergency caesarean section that responded to conservative management.

# DISCUSSION

Pregnancy after stoma surgery for IBD can be a difficult decision for many women. There is little published research about the impact of pregnancy on stoma function, stoma related complications, obstetric and neonatal outcomes. This audit is the largest study of pregnancy outcomes after stoma surgery for IBD. A systematic review (PROSPERO CRD4201919 54521) undertaken as part of the wider PAPooSE study found one paper on eight cases published in 2018 [14]. We have shown that while pregnancy following stoma surgery for IBD is possible, it is associated with significant risk for CS and for stoma related complications. Both observations are key when offering shared decision-making with patients about their obstetric choices and preferences.

Previously patients with stomas often had to rely on anecdotal evidence from other patients and peer support groups when contemplating a pregnancy. Information available from patient support charities such as lleostomy and Internal Pouch Support Association (IA), and Crohn's and Colitis UK could not be based on quantitative research as this was until now lacking. Our study provides timely and much needed quantification of stoma related risks, which in turn informs women with IBD and stomas, and their clinical teams, better when planning pregnancy and pregnancy management.

In our cohort, 73% of pregnancies were delivered by CS compared to a national rate of 29.1% of all deliveries (16.2% emergency, 12.9% elective) [15]. This compares to a rate of 30.9% seen in the general IBD population [16]. The exact reasons for such a high CS rate are not fully understood. In only 19 of 58 (32.8%) elective CS was a clear IBD indication documented. Thirty-two of 58 (55.1%) of CS were in patients who had undergone a subtotal colectomy. Future prospective studies will need to explore obstetric decision making to better inform clinicians and patients whether elective CS is really the optimal method of delivery for women with IBD related stomas. A proportion of patients with an ileostomy due to UC who still have a rectal remnant may have been advised to have a CS to protect sphincter function in the event of future ileoanal pouch anastomosis surgery. It is, however, also possible that some clinicians and patients believed CS to be the delivery method of choice for most pregnancies with IBD related stomas. Reassuringly, the rate of emergency CS in our cohort is similar to that seen in the general population [15].

Given our reported CS rate of 73%, women should be counselled about increased risk of planned CS after IBD surgery with a stoma to facilitate early conversations with their obstetric team about planned CS to avoid further complications. Current guidance [12,17–19] and patient information leaflets should be updated to reflect this risk in the subset of IBD patients with a stoma while highlighting that in general most women with IBD can deliver by vaginal delivery [12,20]. We report three cases of bladder injury during CS, which is much higher than the risk in the general population ranging from 0.1% to 0.3% [21,22]. It is likely that adhesions from previous pelvic surgery increase risk of bladder injury during CS in all women with IBD and does not specifically relate to the presence of a stoma.

Our data shows that women who have a pregnancy after stoma surgery for IBD have slightly worse infant outcomes than the general population, but overall infant outcomes were good. Nineteen per cent of births were before 37 weeks' gestation compared to 7.3% of all deliveries in England and 17% of babies had a birth weight of less than 2,500 g (World Health Organisation definition of low birth weight) compared to 3% in England [15]. This increase in premature delivery and low birth weight may perhaps be driven by IBD disease activity, which would be best assessed with objective measures in a prospective study. It is also possible that altered abdominopelvic anatomy and metabolic deficiencies may also contribute.

There was a high rate of serious stoma complications at 24%, though most were managed conservatively. Patient education early in pregnancy should focus on recognition of stoma complications to allow for timely assessment and where needed intervention. Clinicians and stoma care teams should be aware of the one in four risk of pregnant IBD patients experiencing stoma related complications. Close involvement of the patient's stoma care team should be sought as they are best placed to advise on potential mild to moderate stomal complications and how to manage these during pregnancy, and specifically advise on need to change stoma appliances or application. Interestingly, we found that all stoma complications occurred in patients with ileostomies but not in those with colostomies. Further studies are required to explore this finding and the potential for associated pathophysiology.

This study has important findings for clinicians and researchers and women living with IBD. Specifically, there is a high rate of CS in this population, and this can be associated with additional complications. Obstetric teams should discuss this with patients early in pregnancy. There may also be a need to flag higher risk cases to general surgical colleagues to support challenging abdominal access.

The paucity of data in this field coupled with the findings of this study highlight the need for research programmes in this area of maternal health spanning many subspecialty interest areas. With an obstetric focus, these are optimal antenatal management including frequency of foetal growth scans, and a better understanding of reasons for CS and patient-clinician decision-making around methods of delivery. For gastroenterologists this might include the identification of those at highest risk of flares, optimising IBD prior to conception and ensuring optimisation of biological agents in pregnancy. Colorectal surgeons may wish to consider identification of strategies to manage intestinal obstruction in this context, and strategies to prevent or mitigate stoma complications.

The main strength of our work lies in the multicentre approach of study and the focus on both maternal and foetal outcomes. The limitations of this audit include the retrospective nature and the variable case identification. Due to the retrospective nature of the audit data on disease course prepregnancy, and time from surgery to pregnancy or type of surgery were not collected. However, the retrospective study design is useful for providing preliminary data to inform future prospective studies and may provide valuable clinical information for women while more time-intensive prospective studies are underway.

Data for some patients was incomplete and individual centres were responsible for case identification. Some larger centres had an IBD-pregnancy database, others relied on clinical coding while some entered patients based on personal clinician recollection of their pregnant IBD patients. The variable case identification may mean that some cases will not have been included in the data, particularly from those centres that relied on personal clinician recollection. Clinicians are more likely to remember those patients that have



a complication than those who have a smooth pregnancy. A future prospective study would minimise these limitations. There is also no reliable data on less serious stoma complications such as short-lived obstructive episodes, small parastomal hernias, stoma issues addressed by a stoma care specialist, and transient prolapses. Patients may have experienced these complications but dealt with them at home and not felt the need to report these to their obstetric, gastroenterology, stoma care or surgical team. Further investigation that includes direct patient reported outcomes and experience would establish the wider incidence of stomal complications in pregnancy.

In conclusion, women with IBD and stoma experience different pregnancies than the general population. Women with IBD need to be able to make informed decisions about the potential risks of pregnancy, on both them and their unborn child. The data collected as part of this study highlights an increased risk of CS and a high risk of stoma related complications. Further work is needed to collect prospective data, including patient reported outcomes, to gain a better understanding of on the impact of pregnancy after stoma surgery for IBD. Future studies may also look to gather prospective data on the wider stoma patient cohort, not just those with IBD.

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SD acknowledges the financial support of NHS Research Scotland (NRS), through NHS Lothian. The funding bodies did not contribute to the article.

## CONFLICT OF INTERESTS

SB is the Digital Marketing Manager for Bullen Healthcare, a Dispensing Appliance Contractor. This work was carried out in a personal capacity and in her own time and reflects personal views and not those of her employer. CPS has received unrestricted research grants from Janssen and, AbbVie, has provided consultancy to Arena, Galapagos, Dr Falk, AbbVie, Takeda, Fresenius Kabi and Janssen, and had speaker arrangements with Celltrion, Dr Falk, AbbVie, Janssen, Pfizer and Takeda. MJB reports grants from Vifor International and Tillotts Pharma, travel costs and meeting expenses from Tillotts Pharma, and personal fees from Vifor International, outside the submitted work. PC has received speaker fees from Shire, Abbvie, MSD, Warner-Chillcott and Falk pharma. He has received educational grants from Warner Chilcott, MSD and Ferring pharmaceuticals. He has served as an Advisory Board member for Falk pharma. SD received payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Takeda, Dr Falk. SD received support for attending meetings and/or travel from Abbvie, Takeda, Dr Falk, Janssen. RC received speaker/advisory board fees from Falk, Takeda, Ferring and Janssen. KBK received honoraria for consultancy from Amgen, Janssen, and PredictImmune, for speaker arrangements from Takeda, and Janssen and support for conference attendance fees from Janssen, and Takeda. All other authors declare no conflict of interest.

#### AUTHOR CONTRIBUTIONS

SB and NSF conceptualised the study after the Bowel Research UK (BRUK) event to promote research in problems experienced by IBD patients with stomas and highlighting need for better information for IBD patients with stomas who are planning pregnancy and developed the PAPooSE research team. PPI was provided by SB and ND throughout. SB, CPS and MB designed the audit protocol. CPS, MG, MS, EL, SIK, JL, JB, MB, SD, SS, HJ, LS, SM, BKK, RC, ER, AL and PC provided the study data. CPS accessed and verified the data. Statistical analysis was completed by CPS. CPS, SB, MJB and NSF provided analysis and first interpretation of results. TG interpreted the obstetric data. MJL interpreted the surgical data. SB and CPS drafted the manuscript with all authors reviewing and subsequently approving the final manuscript.

#### DATA AVAILABILITY STATEMENT

Summary data will be available on publication (with no end date) upon reasonable request to Christian Selinger (christian.selinger@web.de).

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#### **APPENDIX 1**

#### THE PAPOOSE STUDY GROUP

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