

Identifying Key Predictors of Metastatic Cutaneous Crohn's Disease: A Case-Control Study

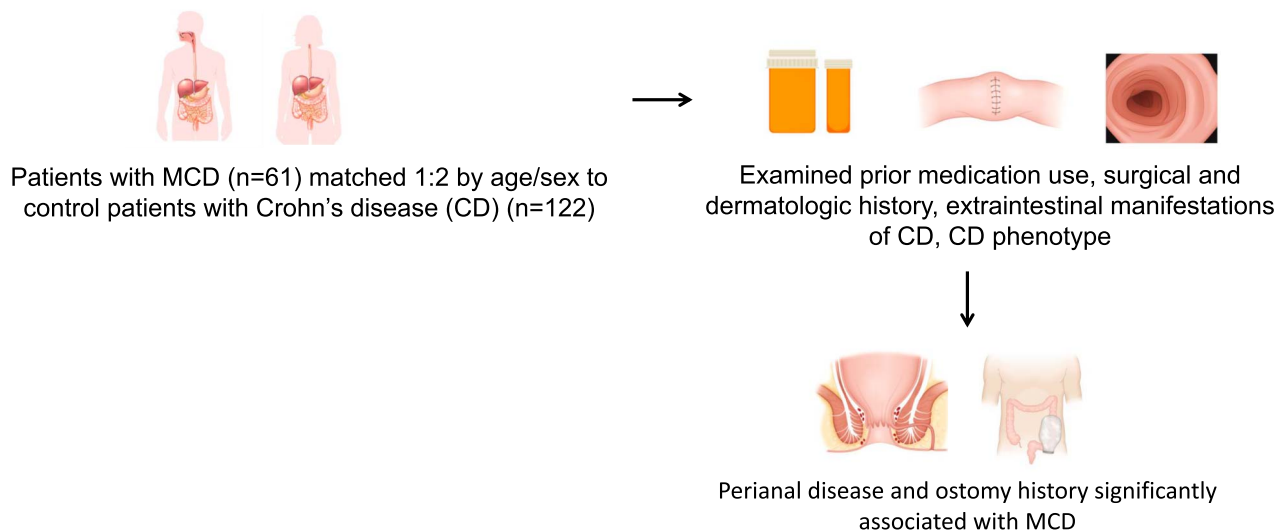
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INTRODUCTION: Metastatic cutaneous Crohn's disease (MCD) is a rare cutaneous manifestation of Crohn's disease (CD) with significant morbidity, yet understanding is limited to case reports and small series. We aimed to identify risk factors associated with MCD development.

METHODS: This retrospective case-control study (January 2016–January 2024) included patients with MCD confirmed using Delphi Panel criteria and controls with gastrointestinal CD, matched 1:2 by age and sex. Demographic factors, CD characteristics, medication history, surgical history, and extraintestinal manifestations were assessed by chart review. Odds ratios were calculated using conditional logistic regression.

RESULTS: Among 474 patients screened, 61 cases were matched with 122 controls. 77.0% were women with no significant differences in smoking history or body mass index between groups. Factors significantly associated with increased MCD odds included perianal CD (OR 6.79, 95% CI 1.47–31.36, $P = 0.014$) and ostomy history (OR 72.65, 95% CI 3.50–1,505.92, $P = 0.006$).

Case-control study looking for risk factors associated with metastatic cutaneous Crohn's disease (MCD)



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DISCUSSION: These findings represent an important step toward understanding MCD's pathogenesis and may inform future translational studies.

KEYWORDS: cutaneous Crohns; metastatic Crohns; extra-intestinal manifestations

ABBREVIATIONS: ACG, American College of Gastroenterology; AIC, Akaike information criterion; BIC, Bayesian information criterion; CD, Crohns disease; IBD, inflammatory bowel disease; ICD-10, International Classification of Diseases; IRB, Internal Review Board; LR, Likelihood ratio; MCD, metastatic cutaneous crohns disease; PPV, positive predictive value; RPDR, research patient data registry; STROBE, strengthening the reporting of observational studies in epidemiology; TNF, tumor necrosis factor

SUPPLEMENTARY MATERIAL accompanies this paper at <http://links.lww.com/AJG/D915>

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INTRODUCTION

Crohn's disease (CD) is a chronic, relapsing form of inflammatory bowel disease (IBD) that can involve any part of the gastrointestinal tract, primarily affecting the small and large bowel. The prevalence of IBD is rising worldwide, with CD affecting over 780,000 Americans annually (1,2). It is characterized by transmural noncaseating granulomatous inflammation often leading to bowel strictures, fistulas, and abscess formation. Ocular, oral, articular, and cutaneous findings can also occur (3) with cutaneous manifestations complicating up to 44% of CD cases (4,5). Among these, metastatic cutaneous Crohn's disease (MCD) represents a rare and poorly understood condition that contributes significantly to disease morbidity (6).

The cutaneous complications of CD are multiple, including reactive neutrophilic lesions (pyoderma gangrenosum, leukocytoclastic vasculitis, erythema nodosum, and Sweet syndrome), epidermolysis bullosa and similar acquired blistering diseases, nutritional deficiency-associated dermatoses, treatment-associated rashes such as paradoxical rashes, and mucocutaneous CD itself, either as contiguous skin disease or noncontiguous (metastatic) CD (6–8).

MCD, defined as distant, noncaseating granulomatous lesions not contiguous with the gastrointestinal tract, has a highly variable clinical morphology most commonly characterized by involvement of the groin and genitals (7,9,10). The epidemiology, natural course, and optimal management remain largely unclear and onset does not necessarily correlate with gut disease and may precede the diagnosis of luminal CD (8,11). MCD can be disabling for patients due to painful fissuring, swelling, ulceration, dysuria, and dyspareunia (10,12,13). Management is similar to that of systemic CD, including corticosteroids, immunomodulators, and biologics or small molecules (advanced therapies), yet MCD may be recalcitrant to treatment.

The pathophysiology of MCD is not well understood. It has been hypothesized that MCD shares similar underlying inflammatory pathways with CD because it exhibits granulomatous inflammation, consisting of macrophages, multinucleated giant cells, and lymphocytes within the dermis and subcutaneous tissue (6). The presence of granulomas suggests a dysregulated immune response, a phenomenon also observed in luminal CD (6). The pathophysiology of MCD involves multiple proposed mechanisms centered on aberrant immune responses, including gut-primed T cells inappropriately homing to ectopic skin sites, deposition of circulating microbial antigens from intestinal sources that trigger distant granulomatous inflammation, T-cell mediated type IV hypersensitivity reactions, cross-reactivity between skin and gut bacterial antigens in genetically susceptible individuals, and dysregulation of the IL-23/Th17 inflammatory pathway that

is implicated in both intestinal and cutaneous manifestations of CD (1,10,13). Whether MCD represents its own distinct immunologic entity or merely an extension of systemic disease remains unresolved. Despite the profound impact of MCD, current available literature is limited to case reports and small case series.

To address this gap, we conducted a case-control study consisting of the first cohort of Delphi-validated MCD cases and age/sex matched controls, ultimately aiming to identify risk factors and potential triggers that can lead to MCD development. We hypothesized that cases with MCD would demonstrate distinct CD characteristics or exposures, reflecting a unique pathophysiology involving dysregulated gut-skin immune axis. With this study, we hope to contribute to the existing understanding of MCD and improve recognition to support earlier diagnosis, optimize treatment strategies, and ultimately improve patient outcomes. We also sought to validate *ICD-10* codes to aid in more accurate identification of patients with MCD in future studies.

METHODS

Study design

We conducted a retrospective case-control study of patients in the Mass General Brigham health system between January 1, 2016 and January 8, 2025. Our study was approved under the Brigham IRB (Protocol #2015P000838) and reported in alignment with STROBE guidelines for observational studies. Control patients were age and sex-matched to cases at a 2:1 ratio. This ratio was based on pilot data which determined a 1:2 case-control ratio would provide 80% power to detect an odds ratio of 2 or greater at a significance level of 0.05, assuming an exposure prevalence of at least 15% in controls. Chart review was performed primarily by 2 authors for eligibility (K.S., J.E.) and by 2 authors for data extraction (N.M.B., E.A.). Discrepancies were resolved by consensus and/or by consultation with senior authors (A.P.C., R.S.D.).

Patient selection

Cases. The case cohort was created using the Mass General Brigham Research Patient Data Registry (RPDR) by identifying patients with *ICD-10* codes associated with MCD (K50.90, K50.918, K52.9, K50, and/or K13.4). These patients were then verified through manual chart review applying diagnostic criteria established by a previously conducted Delphi Panel (14). Patients with clinical findings consistent with MCD as determined by these criteria were classified as cases for this study. In brief, for genital or other (nonoral) cutaneous MCD, diagnosis required 1 major plus 1 minor criterion, 2 major criteria, or 3 minor criteria.

Major criteria included genital swelling, knifelike ulcers of the genital, inguinal, or intertriginous skin, and lymphedematous changes of the genital skin. Minor criteria included perianal skin tag, genital fissuring, nonhealing genital ulcerations with negative herpes simplex virus testing, a cutaneous biopsy suggestive of MCD, and a diagnosis of IBD. Please refer to Ebriani et al (14) for complete description of diagnostic criteria.

Controls. Controls were identified from the RPDR as patients with CD (*ICD-10* codes K50.00-K50.919) diagnosed by a gastroenterologist who had also been seen by dermatology for unspecified benign nevi (*ICD-10* code D22.9). Control patients were age (within 10 years) and sex-matched to cases at a 1:2 ratio and verified through manual chart review. To be eligible as controls, patients required *ICD-10* diagnosis of CD without evidence of MCD, and a documented dermatology evaluation with a diagnosis of melanocytic nevi. This selection strategy controlled for patient-specific factors including access to dermatologic care and exposure to dermatologic education.

Data collection

Data on demographics, disease characteristics, and treatment history including demographic data, smoking status, Montreal CD classification, noncutaneous extraintestinal manifestation of CD including arthropathy and uveitis, non-MCD cutaneous conditions associated with IBD (pyoderma, erythema nodosum), and medication use before MCD development were collected through a combination of query of the RPDR data and verification by manual chart review.

ICD10 code validation

ICD-10 codes were collected using RPDR. Sensitivity and specificity analyses were performed using inclusion in the validated MCD cohort as reference.

Table 1. Demographic characteristics of cases with metastatic cutaneous Crohn's disease and age/sex-matched controls

Characteristic	Cases	Controls	Pvalue
	N (%) or mean \pm SD N = 61	N (%) or mean \pm SD N = 122	
Age	41.7 (15.4)	42.6 (14.2)	0.181
Ever smoker	18 (29.5%)	31 (25.4%)	0.532
Body mass index	28.1 (\pm 8.31)	26.7 (5.8)	0.239
Female sex	47 (77.0%)	94 (77.0%)	
Race			
White	54 (88.5%)	114 (93.4%)	0.264
Black	1 (1.6%)	3 (2.45%)	
Asian	1 (1.6%)	1 (0.82%)	
Two or more races	3 (4.9%)	2 (1.63%)	
Other	2 (3.3%)	2 (1.63%)	
Ethnicity			
Non-Hispanic	57 (93.4%)	113 (92.6%)	0.403
Unknown	3 (4.91%)	9 (7.37%)	

P values calculated using univariate conditional logistic regression to account for paired data structure (1:2 matching). Due to sparse data, race category is calculated as White/non-White binary.

Statistical analysis

All analyses were performed using R version 4.2.0 (R Foundation for Statistical Computing, Vienna, Austria). Univariate conditional logistic regression was performed to assess the association between individual variables and MCD status, with adjustment for multiple comparisons using the Benjamini-Hochberg false discovery rate correction. Variables with significant associations at the univariate level ($P < 0.05$) were considered for the multivariate conditional logistic regression model. All variables demonstrated acceptable collinearity in assessment with pairwise correlations (absolute $r < 0.7$). Data on Montreal classification were not noted in the documentation for a small percentage of patients. Montreal location (L1-L4, p) had 8 missing values (4.37%), Montreal behavior (B1-B3) had 6 missing values (3.28%), and Montreal age (A1-A3) had 4 missing values (2.19%). Body mass index (BMI) data were not recorded for 3 patients (1.64%). Observations missing data for the specific variable being analyzed were excluded from that model.

Outcome measures

The outcome measure for this case-control study was the identification of factors associated with MCD, including demographics, smoking status, CD phenotype (Montreal classification), medication exposure (systemic corticosteroids, antibiotics, immunomodulators, advanced therapies), surgical history (intestinal resections such as colectomy or small bowel resection, other IBD-related surgeries including ostomy), and comorbid autoimmune/inflammatory conditions (cutaneous, mucosal, articular, and ocular).

RESULTS

Demographics

From an original screen of 474 potential case patients, 61 cases were identified who met the validated MCD Delphi criteria, and age/sex matched with 122 controls. Demographic analysis confirmed successful matching based on age (41.7 ± 15.4 vs 42.6 ± 14.2 years, $P = 0.181$) and sex (77.0% women in both groups) (Table 1). There were also no significant differences in baseline BMI (28.1 ± 8.31 vs 26.7 ± 5.8 , $P = 0.239$) or smoking history (29.5% vs 25.4%, $P = 0.532$). Most participants were White (88.5% of cases, 93.4% of controls) and non-Hispanic (93.4% of cases, 92.6% of controls), and did not display significant differences in racial ($P = 0.264$) or ethnic distribution ($P = 0.403$). Treatment outcomes for this cohort have been previously reported (15) and included topical and intraleisional steroids, systemic corticosteroids, antibiotics immunomodulators, and biologic agents.

Risk factors of MCD

Univariate analysis revealed several factors significantly associated with MCD (Figure 1). Among CD characteristics, penetrating disease behavior (Montreal B3) (OR 3.33, 95% CI 1.58–7.01, $P = 0.014$) and perianal disease involvement (OR 9.63, 95% CI 4.03–22.99, $P < 0.001$) were significantly associated with MCD. In addition, colonic involvement (Montreal B2) showed a trend toward increased risk, whereas nonstricturing, nonpenetrating disease (Montreal B1) seemed negatively associated with MCD. However, neither reached statistical significance after adjustment for multiple comparisons. History of a colectomy increased odds of MCD (OR 4.00, 95% CI

Montreal Classification for Crohn's Disease

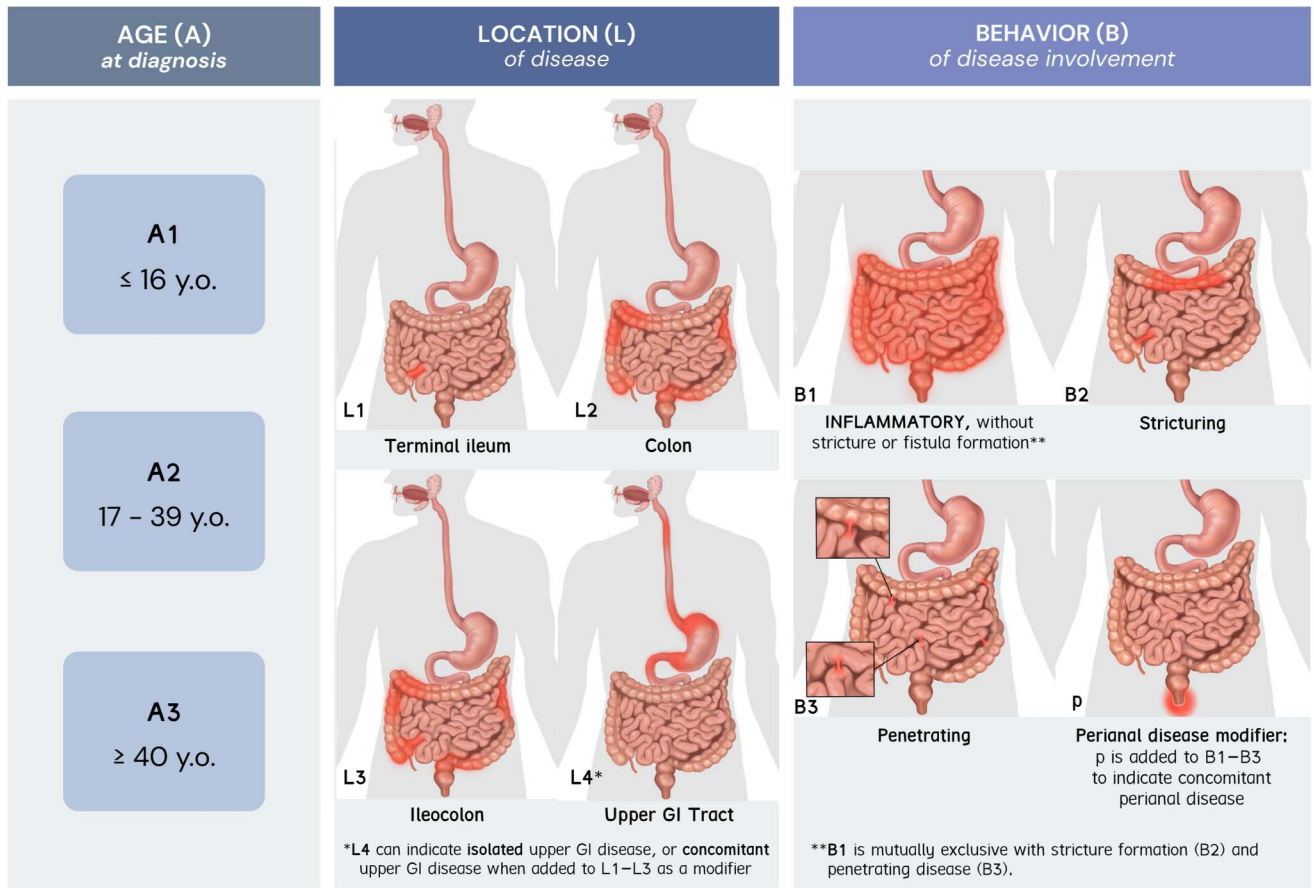


Figure 1. Montreal classification for Crohn's disease.

Table 2. Multivariate model of risk factors of metastatic cutaneous Crohn's disease

Variable	Cases (n = 61) Mean (SD) or N (%)	Controls (n = 122) Mean (SD) or N (%)	Odds (95% CI)	P-value
BMI	28.07 (8.31)	26.75 (5.82)	1.04 (0.96, 1.12)	0.286
Ever smoker	18 (29.5%)	31 (25.4%)	1.34 (0.30, 5.99)	0.704
Hidradenitis suppurativa	14 (23.0%)	8 (6.6%)	2.74 (0.30, 24.93)	0.371
All tumor necrosis factor-alpha inhibitor	48 (78.7%)	92 (75.4%)	0.35 (0.07, 1.68)	0.187
Ostomy history	35 (57.4%)	10 (8.20%)	72.65 (3.50, 1,505.92)	0.006 *
Colectomy history	35 (57.4%)	35 (28.7%)	0.35 (0.03, 4.07)	0.402
Montreal behavior p (perianal disease modifier)	43 (81.1%)	31 (25.4%)	6.79 (1.47, 31.36)	0.014 *
Montreal behavior B3 (penetrating)	36 (65.5%)	44 (36.1%)	1.34 (0.25, 7.29)	0.734
Montreal location L1 (ileal)	4 (7.5%)	31 (25.4%)	0.82 (0.14, 4.67)	0.823

N = 170. likelihood ratio = 67.57, P < 0.001, Akaike information criterion = 62.87, Bayesian information criterion = 82.18.
*P < 0.05.

Table 3. Sensitivity and specificity of ICD-10 codes in identifying metastatic cutaneous Crohn's disease

	ICD-10 code					
	K50.00	K50.918	K52.9	K50.90	L92.9	K13.4
Sensitivity (%)	37.7	52.5	67.2	91.8	29.5	—
Specificity (%)	27.0	76.2	24.6	10.7	98.4	—
Positive predictive value (%)	20.5	52.5	30.8	33.9	90.0	—
Negative predictive value (%)	46.5	76.2	60.0	72.2	73.6	—

This table presents validation metrics (sensitivity, specificity, positive predictive value, and negative predictive value) for select ICD-10 codes in identifying patients with metastatic cutaneous Crohn's disease. K50.00: Crohn's disease of small intestine with complications; K50.918: Crohn's disease, unspecified, with other complication; K52.9: noninfective gastroenteritis and colitis, unspecified; K50.90: Crohn's disease, unspecified, without complications; L92.9: granulomatous disorder of skin and subcutaneous tissue, unspecified. No patients in our cohort had K13.4 (Granulomatous disease of oral mucosa), resulting in the inability to calculate validation metrics for this code.

1.91–8.37, $P = 0.003$). In fact, having history of any IBD-related bowel surgery (OR 3.49, 95% CI 1.71–7.13, $P = 0.006$) demonstrated significant risk. Among comorbidities and medication exposures, hidradenitis suppurativa (OR 7.00, 95% CI 1.97–24.9, $P = 0.021$) and infliximab use before MCD-onset (OR 2.40, 95% CI 1.28–4.51, $P = 0.04$) demonstrated an

increased odds of developing MCD. Other factors including other previous medication use and presence of other dermatologic comorbidities did not show significant associations. Supplementary Table 1 (see Supplementary Digital Content, <http://links.lww.com/AJG/D915>) presents the complete results of the univariate analysis.

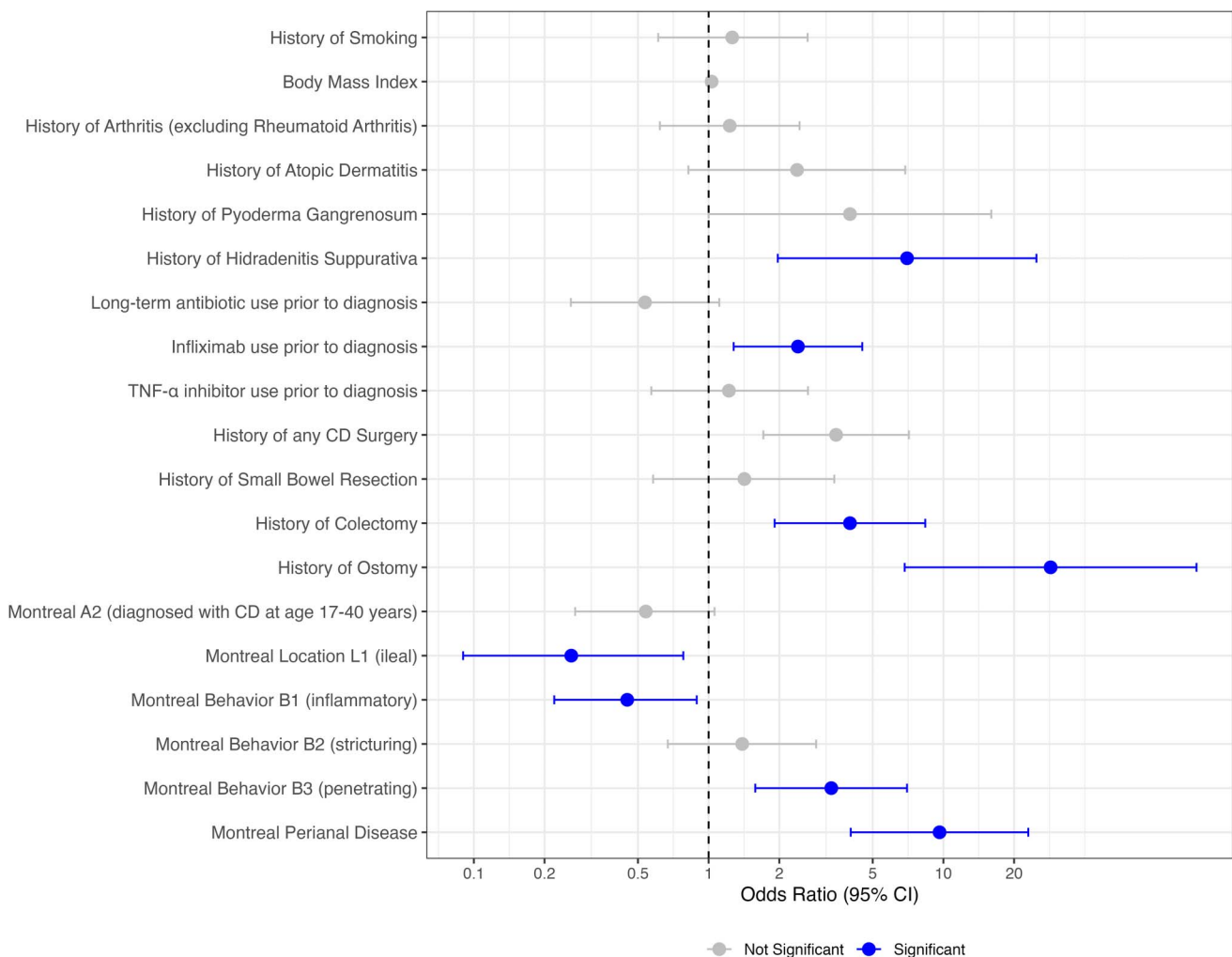


Figure 2. Select univariate covariates of metastatic cutaneous CD. CD, Crohn's disease.

In the multivariate model, 2 factors were independently associated with MCD: perianal disease involvement (OR 6.79, 95% CI 1.47–31.36, $P = 0.014$) and history of an ostomy (OR 72.65, 95% CI 3.50–1,505.92, $P = 0.006$). The observed association for an ostomy history was particularly strong, although the confidence interval was wide due to the low (but expected) frequency of an ostomy among controls. Other variables in the multivariate model, including Montreal behavior classifications, did not retain statistical significance. Table 2 presents the complete results of the multivariate analysis.

A sensitivity analysis was also conducted that excluded patients who demonstrated predominantly peristomal MCD involvement ($n = 2$ cases and their associated $n = 4$ matched controls) to ensure misdiagnosis of conditions such as peristomal dermatitis or peristomal pyoderma gangrenosum were not confounding our results. In addition, we examined timing of surgery relative to MCD development to ensure surgery represented a true risk factor (rather than a treatment) for MCD. In total, of the 38 case patients with CD-related surgical history, 32/38 (84.2%) had at least 1 surgery documented before MCD development. This includes those with ostomy history, 28/36 (77.8%) of which had their ostomy placement before MCD development.

ICD-10 code validation

In ICD-10 code analysis (Table 3), K50.90 (CD, unspecified, without complications) demonstrated the highest sensitivity at 91.8%, but also very poor specificity (10.7%) (Table 3). L92.9 (Granulomatous disorder of skin and subcutaneous tissue, unspecified) had the highest specificity (98.4%) and positive predictive value (90.0%), although its sensitivity was low (29.5%). K50.00 (CD of small intestine with complications) performed poorly across all metrics, with particularly low specificity (27.0%) and positive predictive value (20.5%). K13.4 (Granulomatous disease of oral mucosa) could not be evaluated because no patients in the cohort had this code assigned.

DISCUSSION

This study aimed to identify risk factors of the development of cutaneous CD. To our knowledge, this is the largest single-center adult analysis and the first to use validated Delphi Panel diagnostic criteria (14).

The demographics of our case cohort aligns with established patterns in previously reported IBD and MCD cohorts, including smoking rates in the general CD population (16), and recent trends in increasing BMI (17,18). Regarding gender distribution, our sample demonstrates moderate female predominance of 77.0%, reflecting the historically recognized female skew in CD and MCD, although some recent MCD cohorts have also demonstrated closer to gender parity (10). Our reported Montreal Age distribution is consistent with previous CD data that 25%–35% of diagnoses occur before age 18, with most cases presenting between 15 and 30 years (19).

Our results also demonstrate a robust and significant association between perianal CD and MCD. After multivariate analysis, patients with MCD were substantially more likely to have perianal disease compared with controls. These findings align with previous review literature similarly observing high rates of concomitant contiguous skin disease in patients with MCD, predominantly perianal disease, particularly for female patients (9). Our study found an even stronger association with perianal

disease than previously reported, potentially related to our cohort's female predominance (Figure 2).

Perhaps most interestingly, patients with MCD in our cohort had significantly higher rates of an ostomy history compared with controls. Ostomy might suggest more severe underlying CD or treatment of MCD itself due to poor medication response. However, previous literature has not found a clear correlation between MCD development and underlying intestinal disease course, and has additionally reported a lack of MCD improvement with bowel resection (1,9,13,20). In addition, when the temporal relationship between abdominal surgery and MCD development was examined, 28 of 36 (77.8%) patients with an ostomy had it placed before MCD development, and 32 of 36 (84.2%) patients with CD-related surgery had at least 1 operation before MCD development. Thus, this observed association is unlikely to purely be treatment-related confounding, although we acknowledge this may contribute in a subset of cases. This raises the possibility that ostomy use or surgery may lead to risk-modifying effects on the skin-gut axis, adding a new dimension to existing pathogenesis theories for MCD. For example, gut microbiome disruption may mediate MCD independent of intestinal disease activity, and such disruption has been well-documented in the course of CD surgery (21).

In addition, altered immune sensitization during ostomy use, where there is cross-exposure between Gram-negative intestinal bacteria and Gram-positive skin flora and dermal antigens may predispose to an aberrant skin immune response and abdominal skin involved in stoma formation is regularly exposed to gut flora. This hypothesis complements existing mechanistic theories including the circulating antigen theory and granulomatous vasculitis theory (1,10,13,22–26).

Regarding ICD-10 code validation for optimal case identification of MCD, of tested codes, our results suggest that K50.90 (91.8% sensitivity) as initial screening followed by L92.9 (98.4% specificity, 90.0% positive predictive value) for confirmation may optimize case identification. Future research should formally evaluate this sequential approach by calculating combined performance metrics through Boolean logic combinations or weighted algorithms.

The association between perianal CD and MCD raise concerns for misattribution including the potential that MCD is being misclassified as perianal CD, and vice-versa. Although disorders such as MCD can share overlapping clinical features with perianal CD, our chart review included careful review of available documentation to minimize misdiagnosis or coding discrepancies. Still, this will likely be a challenge for any retrospective study of MCD until validated guidelines are developed to differentiate these overlapping clinical entities when possible.

The case-control design that we selected for this study is well-suited for investigating rare diseases such as MCD. However, this design carries intrinsic limitations including temporal relationship between risk factors and outcome, as well as generalizability. In addition, despite having 1 of the largest dermatologic IBD patient populations in the nation, the rarity of MCD limits our statistical power, particularly for less common extraintestinal manifestations. This also precluded subgroup analyses, for example assessing risk of MCD by subtype of ostomy. Another consequence of cohort size was that estimated odds ratios for covariates such as ostomy history were imprecise with wide confidence intervals due to the small number of exposed controls,

although this observed proportion was consistent with large cohort studies of ostomy rates among patients with CD in the literature (27). Although the exact estimate should be interpreted with caution, the observed association was strong, suggesting a potentially meaningful relationship that merits further investigation in larger or multicenter studies.

Control patient selection poses limitations. The American College of Gastroenterology recommends routine skin cancer screening for all patients with a diagnosis of IBD regardless of immunologic status (28); however, patients may be more likely to be referred to dermatology in settings of long-term biologic use. By selecting for patients with benign nevi we likely over-selected patients with higher biologic exposure potentially underpowering an ability to detect differences in this exposure between groups.

We intentionally did not match on disease severity in this initial case-control study to avoid potential overmatching because the relationship between severity of luminal CD and MCD remains poorly understood. However, future investigations could incorporate validated indices such as the CD Activity Index or Harvey-Bradshaw Index to more granularly characterize the relationship between intestinal disease activity and cutaneous manifestations. Additional important parameters for future exploration include treatment efficacy and clinical measures such as time to diagnosis.

CONCLUSION

Our findings demonstrate significant associations between MCD and risk factors such as perianal disease and history of an ostomy. Therefore, continued integration of gastroenterology-dermatology approaches and increased awareness of extraintestinal manifestations in patients with CD with these identified risk factors is crucial for this patient population.

CONFLICTS OF INTEREST

Guarantor of the article: Alexandra P. Charrow, MD, MBE.

Specific author contributions: N.M.B.: conceptualization, methodology, investigation, data curation, formal analysis, writing—original draft. K.S.-S.: conceptualization, investigation, data curation, writing—original draft. E.A.: formal analysis, writing—review & editing. J.E.: investigation, resources. K.L.: visualization. D.S.: formal analysis, methodology. J.S.B.: conceptualization, investigation, data curation, writing—original draft, writing—review & editing. R.S.D.: supervision, writing—review & editing. A.P.C.: conceptualization, supervision, data curation, writing—original draft, writing—review & editing.

Financial support: None to report.

Potential competing interests: Dr Barbieri has received consulting fees from Honeydew Care and Sanofi Pasteur. Dr Charrow is the PI for clinical trials with Incyte, Avalo, Insmed, and Sonoma. She is on advisory boards for Incyte and previously UCB. She is on board of directors of the HS foundation.

Data sharing statement: Data is not publicly available due to patient privacy restrictions. Data can be made available upon reasonable request to the corresponding author.

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