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Stoma Care Nurse Consultations Regarding Leakages and Peristomal Skin Complications During the First Year After Ostomy Creation: A Chart Review

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ABSTRACT

In the first year after ostomy creation, affected persons require substantial support to manage potential complications and adjust to their new life situation. This study aimed to describe the number of visits to the stoma care nurse, the occurrence of leakage and peristomal skin complications, and the use of ostomy products to prevent these complications among persons consulting a stoma care nurse during the first year after surgery. A descriptive study was conducted using data from medical charts for 240 adults with ileostomy or colostomy. Persons with an ileostomy were more burdened by leakage and peristomal skin complications and visited the stoma care nurse more often than those with a colostomy. On average, across ostomy types, episodes of leakage and peristomal skin complications each elicited around one additional nurse visit and increased use of supporting ostomy products. Persons undergoing acute surgery, with a high ASA classification, and females experienced more episodes of leakage, peristomal skin complications and nurse visits. A patient-tailored approach based on risk factors, such as surgery type, ASA class and sex, could potentially reduce the occurrence of complications and the associated healthcare resource utilisation, including stoma care nurse visits. High variability in results further underscores the importance of personalised care.

1 | Introduction

For people with diseases such as bowel, bladder and gynaecological cancers, inflammatory bowel disease and diverticulitis, the creation of an ostomy often provides relief from disease sequelae, but it also implies a life-changing situation that the affected person must adapt to [1]. In Sweden, it has been estimated that in 2015, about 43,000 people out of a population of roughly 10 million were living with an ostomy [2, 3], representing around 0.4% of the total population. In the future, the number of people with an ostomy is expected to rise due to an aging population, with risk factors such as colorectal cancer becoming more prevalent [4]. Moreover, with approximately 90 stoma care nurses nationwide, this results in roughly 2 nurses per 1000 people with an ostomy.

An ostomy is an operative intervention in which the colon or ileum is exteriorised to the abdominal skin, providing a diversion for stool or urine [5]. Ileostomies, created from the ileum, typically result in a more liquid and frequent faecal output, implying a higher risk of faecal leakages and peristomal skin complications (PSCs) compared to colostomies. Colostomies, the most common ostomy type, are formed from the colon, resulting in a more solid output [6].

Summary

What does this paper contribute to the wider global community?

- On average, episodes of leakage and peristomal skin complications each elicited around one additional visit to a stoma care nurse and increased use of supporting ostomy products.
- On average, persons with an ileostomy, as well as those who had acute surgery, a high ASA classification or female gender experienced higher rates of episodes of leakage, peristomal skin complications and visits to a stoma care nurse.
- A patient-tailored approach based on risk factors could potentially reduce the occurrence of leakage and peristomal skin complications and hence healthcare resource utilisation, such as stoma care nurse visits.
- A wide range in the rate of visits to a stoma care nurse and the use of supportive ostomy products underscored the need for personalised ostomy care.

Management of an ostomy requires an appliance to collect output, consisting of an ostomy baseplate adhering to the peristomal skin and connected to a collection bag. Leakage of output typically occurs if the baseplate does not fit properly to the ostomy and the area around the peristomal skin, leading to the need for alternative ostomy products or supporting products such as rings/seals, paste, tape or a belt to maintain the fit and function of the baseplate and minimise the risk of leakage episodes [7]. PSCs can arise when the output comes into contact with the skin below the baseplate, causing irritant contact dermatitis [8]. Leakage and PSCs can significantly impact a person's mental, social and physical well-being [9–16]. A constant worry about potential leakage episodes in public is one of the most significant challenges negatively impacting the quality of life for people living with an ostomy [9, 10, 14, 17, 18].

A person scheduled for elective surgery leading to an ostomy typically meets with the stoma care nurse pre-operatively to receive information about life with an ostomy and to identify the most suitable ostomy site. Proper placement on the abdomen enables the person to see and care for the ostomy while avoiding skin folds, previous scars and the beltline. Correct ostomy siting also reduces the risk of leakage and PSCs. However, in cases of acute surgery, there may not be sufficient time for optimal ostomy siting, and the placement can be more challenging due to abdominal distension [19]. High ASA scores have also been shown to increase the risk of PSCs [20].

According to Swedish national guidelines, a person with a newly created ostomy should have regular follow-up visits by a specialised stoma care nurse four to five times during the first year [21]. These visits aim to support the patient in coping with the new situation, provide education to become self-sufficient in ostomy care, and to prevent ostomy complications. These visits also entail the assessment of the ostomy height and diameter, as well as the evaluation of the current ostomy product(s) to ensure an adequate set of applications for the best fitting according to the person's ostomy and peristomal body profile, thereby helping to prevent leakage. The body profile may change over time, and depending on the ostomy and the body profile, the person may need a flat, convex or concave ostomy appliance to prevent ostomy complications [15]. Additionally, the stoma care nurse examines the skin around the ostomy for signs of PSCs or infection. Most cases of PSCs are detected during routine check-ups by the stoma care nurse at the outpatient clinic, or they are the reason prompting the patient to schedule a visit [21].

Sweden has a longstanding tradition of nationwide registration of social and health data. A previous analysis of national data for all people with an ostomy in Sweden described the cost of illness [22]. However, ostomy care consultations, for example, are not captured in the national registries. Consequently, information concerning ostomy-related challenges such as leakage and PSCs, which are typically managed by the stoma care nurse, remains unreported. Chart reviews with registry data linkage, therefore, add important information regarding the full burden of illness. It was hypothesised that leakage and PSCs would require additional professional support for effective management in the first year after ostomy creation, resulting in more frequent visits to a stoma care nurse.

This study aimed to describe the number of visits to a stoma care nurse, the occurrence of leakage and PSCs, and the use of ostomy products to prevent these complications among persons consulting a stoma care nurse during the first year after surgery. Since visits to stoma care nurses and the occurrence of leakage and peristomal skin complications are not captured in any registries, we also conducted medical chart reviews to obtain this information. Additionally, the study aimed to examine patterns and costs of ostomy product usage, the latter in combination with data from a previously published registry study [22].

2 | Methods

2.1 | Design

This study complemented a previous nationwide study conducted by Carlsson et al. 2023, which extracted data from Swedish civil and health registries [22]. The previous study retrospectively followed more than 40,000 persons with an ostomy (40,988 with a colostomy, ileostomy or urostomy) and approximately twice as many matched controls (80,924) from 2006 to 2019, with the aim to describe healthcare resource utilisation and costs up to 10 years after the creation of an ostomy. The population examined in the current study constituted a subset of the nationwide cohort with ostomy in the registry study. The present study was a descriptive, observational study using an incident approach based on retrospective data from medical charts.

2.2 | Setting

Seven stoma care clinics situated in the administrative regions of Stockholm, Östergötland, Halland and Skåne were invited to participate in the study. These regions were primarily

selected based on population size, excluding regions where it was not feasible to gather data on the purchase of ostomy products and/or information from primary care. Additionally, the same regions had been contacted to provide primary care data, which is not available in the national registries. Clinics with available resources to review medical charts accepted the invitation.

2.3 | Sample

The chart review population was identified by convenience sampling performed by the local stoma care nurse from each of the participating clinics. The inclusion criteria comprised the 50 most recently operated persons per clinic, aged 18 years or older, with a colostomy or ileostomy created no later than 31 December 2018. The index date was the date of ostomy creation, and the chart review covered the following 12 months. Exclusion criteria were transverse colostomy and multiple ostomies. Only persons who completed a full 12-month follow-up were included in this publication.

2.4 | Data Collection

The manual extraction of data from electronic medical charts was performed by the local stoma care nurses. The medical charts informed data on demographics and clinical characteristics at index and outcomes following ostomy creation. A predefined structured Excel-based data extraction form, developed by the authors, was used for uniform data extraction from the medical charts. The data extraction forms were assigned a number based on an internal key, set up by the stoma care nurse, where personal numbers were replaced by a running number (1, 2, 3, 4, ..., 50). Ostomy baseplates and bags, as well as supporting products, were categorised based on ATC codes and/or product number as outlined in Table S1. The associated cost was presented in SEK (Swedish krona; 100 SEK was equivalent to 9.58 EUR per 31 December 2019).

2.5 | Linking of Data

The running numbers of the extraction forms were replaced by the corresponding personal identification number in the national registry cohort by the national registry holder (The National Board of Health and Welfare), enabling subsequent linkage to registry data. This allowed episodes of leakage and/or PSCs to be connected to the usage and costs of prescribed ostomy products obtained from the Swedish Prescribed Drug Register.

2.6 | Outcomes

The outcomes of the study included the occurrence of leakage, PSCs and stoma care nurse contacts in the first year after ostomy creation. These outcomes were further analysed by sex, type of surgery (acute, elective) and ASA classification. Furthermore, the use of ostomy baseplates, bags and supporting products, along with their associated costs, was also examined.

2.7 | Data Analysis

The study was descriptive in nature, and it was not designed or powered to enable statistical analysis of inter-group differences. Continuous variables were presented by the mean and standard deviation (SD). Additionally, the median, minimum (min) and maximum (max) values were provided where deemed meaningful for the interpretation of the data. Categorical variables were presented as the absolute number and distribution. Data analyses were performed in SAS version 9.4 (SAS Institute, Cary, NC, USA).

2.8 | Ethical Considerations

All participating clinics and stoma care nurses signed a contract. Ethical approval for the study was given by the Swedish Ethical Review Board Authority (Dnr 2020–06649). The personal identification numbers of the chart review population were only handled by the designated local stoma care nurse and the National Board of Health and Welfare, which extracted data from the Swedish registries. All reported data were anonymised. The research was carried out in accordance with the Declaration of Helsinki.

3 | Results

3.1 | Demographics and Clinical Characteristics

A total of 327 persons were initially included in the study population. However, only those who completed a full 12-month follow-up were included in this publication, resulting in a final sample of 240 persons: 166 with a colostomy and 74 with an ileostomy. Baseline characteristics at index for groups with colostomy or ileostomy, as well as the combined group, are shown in Table 1. The mean age at index was 69.6 years for persons with a colostomy and 59.1 years for those with an ileostomy, reflecting a difference of approximately 10 years. Overall, there was a slightly higher proportion of females than males. The underlying disease was, in most instances, cancer and more than one-third of the sample were classified as ASA class III, indicating severe systemic disease. The majority of the ostomies were permanent, and most surgeries were elective, particularly among those with a colostomy.

3.2 | Leakage and PSCs

Among persons visiting the stoma care nurse for regular check-ups or due to complications, those with an ileostomy more frequently experienced episodes of leakage and PSCs than those with a colostomy in the first year after ostomy creation (Table 2). On average, each person with an ileostomy experienced 1.55 episodes of leakage and 2.73 episodes of PSCs, while a person with a colostomy averaged 0.47 episodes of leakage and 0.99 episodes of PSCs. Almost half of the persons with a colostomy did not experience any leakage or peristomal skin complications, whereas only 7% of persons with an ileostomy remained free from these issues. Across ostomy types, more females than males were reported by the stoma

TABLE 1 | Baseline characteristics at index.

	Colostomy (*n* = 166)	Ileostomy (*n* = 74)	Total (*n* = 240)
Age (years), mean (SD)	69.6 (11.8)	59.1 (17.4)	66.4 (14.6)
Age, *n* (%)			
20–29 years	1 (0.6%)	5 (6.9%)	6 (2.5%)
30–39 years	4 (2.4%)	4 (5.6%)	8 (3.4%)
40–49 years	5 (3.0%)	8 (11.1%)	13 (5.5%)
50–59 years	18 (10.8%)	9 (12.5%)	27 (11.3%)
60–69 years	46 (27.7%)	21 (29.2%)	67 (28.2%)
70–79 years	55 (33.1%)	21 (29.2%)	76 (31.9%)
80–89 years	35 (21.1%)	3 (4.2%)	38 (16.0%)
90+ years	2 (1.2%)	1 (1.4%)	3 (1.3%)
Sex, *n* (%)			
Male	75 (45.2%)	30 (40.5%)	105 (43.8%)
Female	91 (54.8%)	44 (59.5%)	135 (56.3%)
Administrative region, *n* (%)			
Stockholm	39 (23.5%)	35 (47.3%)	74 (30.8%)
Östergötland	7 (4.2%)	11 (14.9%)	18 (7.5%)
Halland	61 (36.7%)	12 (16.2%)	73 (30.4%)
Skåne	59 (35.5%)	16 (21.6%)	75 (31.3%)
Permanent or temporary ostomy, *n* (%)			
Permanent	153 (92.7%)	49 (67.1%)	202 (84.9%)
Temporary	8 (4.8%)	23 (31.5%)	31 (13.0%)
No information	4 (2.4%)	1 (1.4%)	5 (2.1%)
Acute or elective surgery, *n* (%)			
Acute	47 (28.3%)	34 (45.9%)	81 (33.8%)
Elective	119 (71.7%)	40 (54.1%)	159 (66.3%)
Underlying diagnosis for ostomy creation, *n* (%)			
Cancer (unspecified)	102 (61.4%)	50 (67.6%)	152 (63.3%)
Inflammatory bowel disease	4 (2.4%)	7 (9.5%)	11 (4.6%)
Other	60 (36.1%)	17 (23.0%)	77 (32.1%)
ASA classification, *n* (%)			
ASA I: Healthy person	11 (7.3%)	3 (4.6%)	14 (6.5%)
ASA II: Mild systemic disease	70 (46.7%)	37 (56.9%)	107 (49.8%)
ASA III: Severe systemic disease	59 (39.3%)	20 (30.8%)	79 (36.7%)
ASA IV: Severe systemic disease that is a constant threat to life	10 (6.7%)	5 (7.7%)	15 (7.0%)

Note: Results were based on data from medical charts.
Abbreviations: ASA: American Society of Anaesthesiologists' classification of physical health; SD: standard deviation.

care nurse for episodes of leakage and PSCs, as were persons who underwent acute surgery (Table 3). Similarly, a higher ASA classification before surgery was associated with more episodes (Table 4).

3.3 | Stoma Care Nurse Consultations

On average, a person with an ileostomy visited the stoma care nurse 4.45 times during the first year, while this number was 4.01 for a person with a colostomy (Table 5). Similarly, persons with an ileostomy made more telephone calls to the stoma care nurse than those with a colostomy. Across both ostomy types, persons visited the stoma care nurse 4.15 times on average, and the number of visits to the stoma care nurse increased gradually as the number of episodes of leakage or PSCs increased (Figure 1). Persons who experienced at least one episode of leakage had an average of 4.92 visits per person, and this increased to 9.89 visits per person among those who had at least five episodes. Similarly, persons who experienced at least one episode of PSCs had on average 4.61 visits per person, increasing to 7.91 visits per person among those with at least five episodes. This corresponds to each episode of leakage or PSCs eliciting approximately one extra visit to the stoma care nurse. Among persons without leakage and PSCs, the stoma care nurse was on average visited 3.28 times per person (Table 5). Furthermore, when visits to the stoma care nurse specifically due to leakage and/or PSCs were calculated among all persons visiting the stoma care nurse for any reason, it showed that females had more visits than males (2.05 vs. 1.41 visits), persons who underwent acute surgery had more visits than those who had elective surgery (2.40 vs. 1.45 visits), and as the ASA class increased, the number of visits also increased, ranging from 0.84 visits (ASA I + II with colostomy) to 4.40 visits (ASA III + IV with ileostomy) (Tables 3 and 4).

3.4 | Ostomy Products Usage and Cost

The results on ostomy product usage are primarily drawn from registry data unless specified otherwise, as shown in Table 6. Overall, a flat ostomy baseplate was the most common initial choice following the ostomy creation. However, around one third of persons with an ileostomy started on a convex baseplate. Results from the medical charts revealed that starting on a flat baseplate, especially after ileostomy creation, often led to a subsequent switch to a convex baseplate. Conversely, among those initially using a convex baseplate, very few with an ileostomy

TABLE 2 | Episodes of leakage and PSCs recorded by the stoma care nurse during visits for any reason in the first year after ostomy creation.

	Colostomy	Ileostomy	Total
	(*n* = 166)	(*n* = 74)	(*n* = 240)
Episodes of leakage			
Number, *n*	78	115	193
Per person, mean (SD)	0.47 (0.87)	1.55 (2.66)	0.80 (1.72)
Episodes of PSCs			
Number, *n*	159	202	361
Per person, mean (SD)	0.99 (1.46)	2.73 (2.68)	1.50 (2.08)
Episodes of leakage and/or PSCs			
Number, *n*	237	317	554
Per person, mean (SD)	1.43 (2.03)	4.28 (5.10)	2.31 (3.54)
Number of persons experiencing episodes of leakage and/or PSCs, *n* (%)			
0 episode	71 (42.8%)	5 (6.8%)	76 (31.7%)
1 episode	40 (24.1%)	10 (13.5%)	50 (20.8%)
2 episodes	25 (15.1%)	16 (21.6%)	41 (17.1%)
3 episodes	14 (8.4%)	15 (20.3%)	29 (12.1%)
4 episodes	3 (1.8%)	10 (13.5%)	13 (5.4%)
5 episodes	3 (1.8%)	5 (6.8%)	8 (3.3%)
6+ episodes	10 (6.0%)	13 (17.6%)	23 (9.6%)
At least 1 episode of leakage, *n* (%)	51 (30.7%)	42 (56.8%)	93 (38.8%)
At least 1 episode of PSCs, *n* (%)	78 (47.0%)	66 (89.2%)	144 (60.0%)
Episodes of both leakage and PSCs recorded at the same visit, *n* (%)	27 (16.3%)	32 (43.2%)	59 (24.6%)
At least 1 episode of leakage and/or PSCs recorded during study period	34 (20.5%)	39 (52.7%)	73 (30.4%)

Note: Results were based on data from medical charts.
Abbreviations: PSCs: peristomal skin complications; SD: standard deviation.

switched to a flat baseplate, while such a switch was more common among those with a colostomy.

Nearly all persons used between two and four supporting products, with a notable trend indicating the greatest product use among persons with an ileostomy (Table 6). Irrespective of the type of ostomy, the use of supporting products increased in correlation with the frequency of leakage and PSCs (Figure 2). The number of supporting products increased from 3.56 to 4.11 in cases of one or more episodes to five or more episodes of leakage. Similarly, the number increased from 3.41 to 4.09 when experiencing one or more episodes of PSCs to five or more episodes.

The overall costs of ostomy products in the first year after ostomy creation averaged 43,700 SEK per person, with baseplates and bags being the primary cost drivers (Table 7). The most notable cost difference between having a colostomy and an ileostomy was in relation to supporting products, which were approximately three times higher for persons with an ileostomy compared to those with a colostomy.

4 | Discussion

In this retrospective descriptive chart review study, we observed that a large proportion of persons with a newly created ostomy who visited a stoma care nurse in the first year after the creation were extensively burdened by leakage and PSCs. The more episodes of leakage and/or PSCs the persons experienced, the more often the stoma care nurse was consulted, and the more supporting ostomy products were used. In general, persons with an ileostomy were more burdened by leakage and PSCs and, hence, consulted the stoma care nurse more often than those with a colostomy. The average number of follow-up visits for persons with an ostomy met the national recommendations of four to five visits during the first year. However, experiencing episodes of leakage and PSCs resulted in an increased number of stoma care nurse visits.

The role of a stoma care nurse is to provide education and support to people living with an ostomy and to address any concerns with leakage, odour, skin, ostomy complications, stool consistency and appliances [21]. Reducing leakage and PSCs is crucial, as it not only enhances the quality of life for people with an ostomy but also minimises costs to the healthcare system [7, 18, 23]. To obtain a better understanding of the challenges people living with an ostomy face, the Ostomy Life Study was initiated. The first online survey in 2014 included around 4000 participants from 11 countries [9], and it was later expanded to a second survey in 2019, consisting of more than 5000 participants from 17 countries, including Sweden [10–14]. In the Ostomy Life Study 2019, it became apparent that almost 40% of those with access to a stoma care nurse had never contacted one, irrespective of a varying duration since their ostomy surgery [13, 14]. Moreover, among colorectal cancer survivors with an ostomy across five European countries, 22% were unaware of the possibility to consult a stoma care nurse [16]. Swedish persons comprised 11.4% of the total study population, and within this group, the proportion unaware of the option was 24%. In our study, which specifically focused on a subset of persons who visited the stoma care nurse, they had an average of 4.15 visits, thereby meeting the recommended 4–5 visits during the first year after ostomy creation, as outlined in guidelines [21]. However, as with many of the results, there was a large range, with the number of visits varying from 0 to 19. As expected, the number of visits to

TABLE 3 | Episodes of leakage and PSCs recorded by the stoma care nurse during visits for any reason in the first year after ostomy creation, stratified by sex and by acute or elective surgery.

	Male	Female	Acute surgery	Elective surgery
	(*n* = 105)	(*n* = 135)	(*n* = 81)	(*n* = 159)
Episodes of leakage				
Number, *n*	51	142	105	88
Per person, mean (SD) and median (min;max)	0.49 (1.31) 0 (0;10)	1.05 (1.94) 0 (0;15)	1.30 (2.57) 1 (0;15)	0.55 (0.97) 0 (0;4)
Episodes of PSCs				
Number, *n*	137	224	161	200
Per person, mean (SD) and median (min;max)	1.30 (1.95) 1 (0;13)	1.66 (2.17) 1 (0;15)	1.99 (2.65) 1 (0;15)	1.26 (1.68) 1 (0;8)
Episode of leakage and PSCs				
Number, *n*	188	366	266	288
Per person, mean (SD) and median (min;max)	1.79 (3.10) 1 (0;23)	2.71 (3.80) 2 (0;30)	3.28 (5.01) 2 (0;30)	1.81 (2.34) 1 (0;11)
Visits to stoma care nurse				
Number, *n*	148	277	194	231
Per person, mean (SD) and median (min;max)	1.41 (2.03) 1 (0;14)	2.05 (2.35) 1 (0;15)	2.40 (2.89) 2 (0;15)	1.45 (1.74) 1 (0;8)

Note: Results were based on data from medical charts.
Abbreviations: max: maximum; min: minimum; PSCs: peristomal skin complications.

TABLE 4 | Episodes of leakage and PSCs recorded by the stoma care nurse during visits for any reason in the first year after ostomy creation, stratified by ASA classification.

	Colostomy		Ileostomy		Total	
	ASA I + II	ASA III + IV	ASA I + II	ASA III + IV	ASA I + II	ASA III + IV
	(*n* = 81)	(*n* = 69)	(*n* = 40)	(*n* = 25)	(*n* = 121)	(*n* = 94)
Episodes of leakage						
Number, *n*	22	43	39	68	61	111
Per person, mean (SD) and median (min;max)	0.27 (0.65) 0 (0;4)	0.62 (1.02) 0 (0;4)	0.98 (1.35) 0 (0;5)	2.72 (4.02) 1 (0;15)	0.50 (0.99) 0 (0;5)	1.18 (2.41) 0 (0;15)
Episodes of PSCs						
Number, *n*	55	86	89	95	144	181
Per person, mean (SD) and median (min;max)	0.68 (1.12) 0 (0;6)	1.25 (1.78) 1 (0;8)	2.23 (1.66) 2 (0;7)	3.80 (3.88) 2 (0;15)	1.19 (1.50) 1 (0;7)	1.93 (2.74) 1 (0;15)
Episode of leakage and PSCs						
Number, *n*	77	129	128	163	205	292
Per person, mean (SD) and median (min;max)	0.95 (1.45) 0 (0;8)	1.87 (2.49) 1 (0;11)	3.20 (2.62) 3 (0;11)	6.52 (7.65) 3 (0;30)	1.69 (2.18) 1 (0;11)	3.11 (4.89) 2 (0;30)
Visits to stoma care nurse						
Number, *n*	68	101	101	110	169	211
Per person, mean (SD) and median (min;max)	0.84 (1.19) 0 (0;6)	1.46 (1.84) 1 (0;8)	2.53 (1.77) 2 (0;18)	4.40 (4.18) 3 (0;15)	1.40 (1.61) 1 (0;8)	2.24 (2.95) 1 (0;15)

Note: Results were based on data from medical charts.
Abbreviations: ASA: American Society of Anaesthesiologists' classification of physical health; max: maximum; min: minimum; PSCs: peristomal skin complications.

TABLE 5 | Consultations (visits and by telephone) with a stoma care nurse for any reason in the first year after ostomy creation, as well as visits due to leakage and/or PSCs among those experiencing leakage and PSCs.

	Colostomy (*n* = 166)	Ileostomy (*n* = 74)	Total (*n* = 240)
Consultations (visits and by telephone) with stoma care nurse			
Number, *n*	977	504	1481
Per person, mean (SD) and median (min;max)	5.89 (3.24) 5.0 (1;18)	6.81 (4.55) 6 (2;26)	6.17 (3.71) 5 (1;26)
Visits to stoma care nurse			
Number, *n*	666	329	995
Per person, mean (SD) and median (min;max)	4.01 (1.94) 4.0 (0;13)	4.45 (2.88) 4.0 (2;19)	4.15 (2.27) 4.0 (0;19)
Telephone contact with stoma care nurse			
Number, *n*	309	174	483
Per person, mean (SD) and median (min;max)	1.86 (2.09) 1.0 (0;90)	2.35 (2.51) 2.0 (0;12)	2.01 (2.23) 1.0 (0;12)
Number of visits to stoma care nurse per person according to episodes of leakage and PSCs, mean (SD) and median (min;max)			
Among persons with no episodes of leakage or PSCs recorded	3.28 (1.56) 3.0 (0;7) *n* = 69	3.40 (0.89) 3.0 (3;5) *n* = 5	3.28 (1.52) 3.0 (0;7) *n* = 74
Among persons with episodes of both leakage and PSCs recorded at the same visit	5.00 (2.51) 4.0 (2;13) *n* = 28	5.63 (3.87) 4.5 (2;19) *n* = 32	5.33 (3.29) 4.0 (2;19) *n* = 60

Note: In some medical charts, it was not specified whether the consultation occurred as a visit or by telephone. Thus, the total count of visits and contact by telephone does not necessarily match the number specified as consultations. Results were based on data from medical charts.
Abbreviations: max: maximum; min: minimum; PSCs: peristomal skin complications; SD: standard deviation.

the stoma care nurse increased with an increasing number of episodes of leakage and/or PSCs; one extra episode of leakage or PSCs elicited around one extra visit to the stoma care nurse. It has earlier been demonstrated that the support from stoma care nurses may increase the quality of care, decrease the incidence of ostomy-related complications, and thus quality of life and healthcare costs [24, 25].

Leakage and PSCs are well-known challenges for people living with an ostomy. When these complications occur, they often feel that their life has been limited. In a survey among rectal cancer survivors with a permanent colostomy, 58% of more than 2000 participants from five countries reported leakage: 47% less than once a week and 11% more than once a week [16]. The Ostomy Life Studies showed that more than 90% of the persons living with an ostomy who answered the questionnaires worried about leakage to some degree [9, 10]. Furthermore, the first Ostomy Life Study found that 76% of the participants experience leakage to some extent, ranging from a very high degree to a low degree [9]. In the second Ostomy Life Study, 76% and 83% of persons with a colostomy or an ileostomy, respectively, reported leakage under the baseplate at least once in the previous month [13]. In our study, among persons who consulted a stoma care nurse, 38.8% had experienced at least one episode of leakage in the first year after the ostomy creation. In accordance with the Ostomy Life Study, we found that persons with an ileostomy experienced more leakage episodes than those with a colostomy [13, 26, 27]. This difference may be attributed to more liquid output associated with an ileostomy [6]. Additionally, nearly half of the persons who underwent ileostomy surgery in our study had acute surgery, which may have influenced the incidence of leakage. Acute surgery makes it more challenging for the surgeon to construct the ostomy, as there is less time for pre-operative planning, such as ostomy siting [19].

A higher frequency of leakage has been found to significantly correlate with more episodes of PSCs, as faecal leakage on the peristomal skin increases the risk of PSCs [28]. The Ostomy Life Study reported that up to 88% of the participants suffered from PSCs [12], and 60.6% of the persons in our study had experienced at least one episode of PSCs. Comparing frequencies of leakage and PSCs can be challenging due to variations in study design and methodologies. However, the results from many studies, including ours, clearly show that leakage and PSCs are common problems faced by many people living with an ostomy. Therefore, managing these issues is crucial, as they impact the quality of life severely [9–15, 28, 29]. As is the case with leakage, the occurrence of PSCs depends on the type of ostomy [30]. This is supported by our results, where persons with an ileostomy had more episodes than those with a colostomy.

Our results also revealed that females visiting the stoma care nurse experienced more episodes of leakage and PSCs than

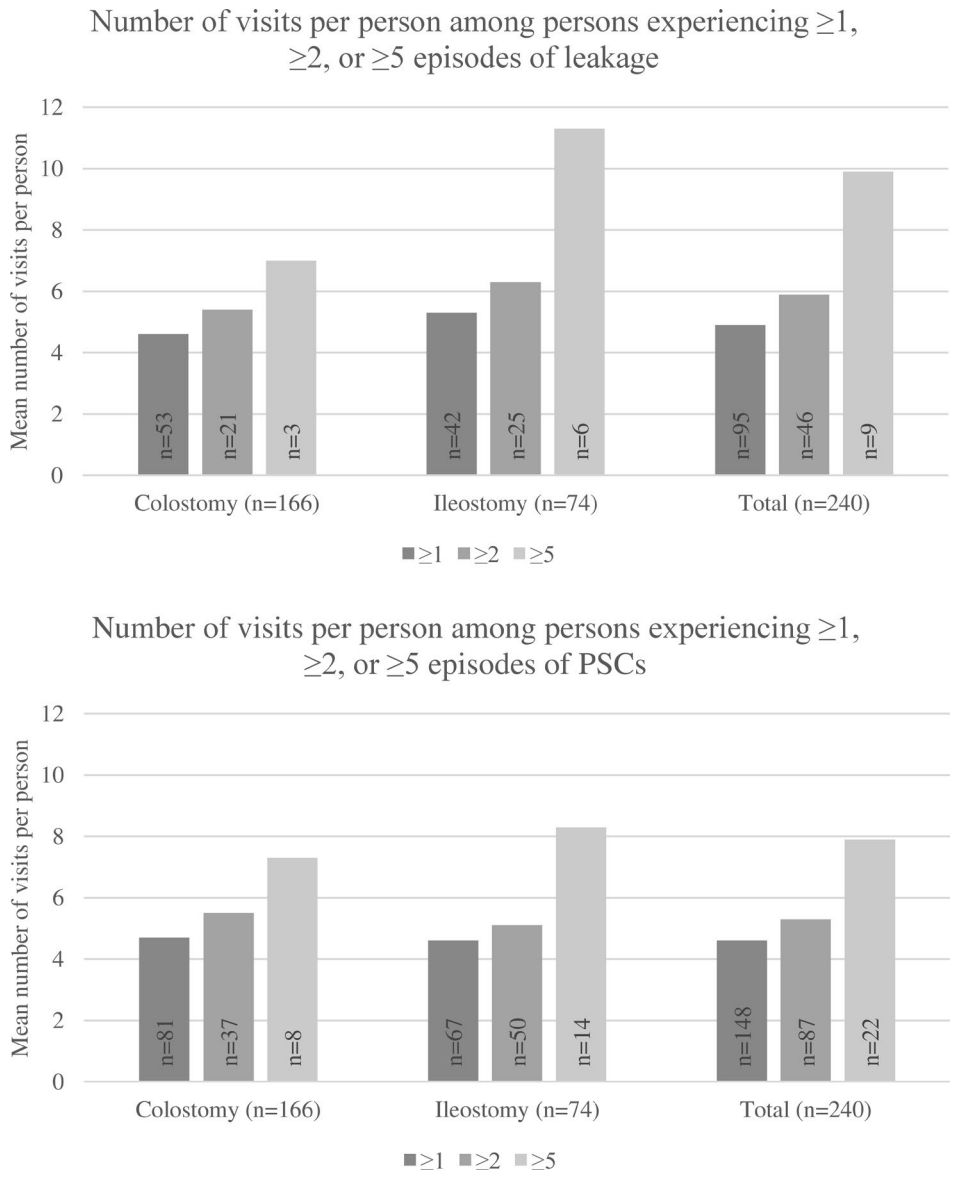

FIGURE 1 | Number of visits to a stoma care nurse in the first year after ostomy creation among persons experiencing leakage and/or PSCs according to the frequency of these issues. PSCs, peristomal skin complications. Results were based on data from medical charts. Please refer to Table S2 for values of mean, standard deviation, median, as well as minimum and maximum.

males, which resulted in more stoma care nurse visits. In accordance with this, a previous study reported that women in a community setting more frequently reported leakage than men [27]. The differences in body configuration between men and women might contribute to this, as women generally have more subcutaneous abdominal fat [31], which can affect how well the ostomy appliance adheres [15]. Moreover, previous studies have suggested that men, in general, are less likely to seek healthcare support [32]. In a Swedish clinical study, it was observed that a colostomy height below 5 mm, which makes achieving a proper fit with the ostomy appliance more difficult, was significantly more common in women and following acute surgery, as was the use of a convex baseplate compared to colostomies with a height above 5 mm [24]. It has also been shown that ASA scores III–IV are predictors for the persistence of peristomal complications for at least the first 30 days after ostomy surgery [20].

Persons with an ostomy exhibit diverse peristomal body profiles, and it may change over time [5]. In the initial 3 months after ostomy creation, the ostomy's diameter and height typically decrease [24, 33], and changes in body weight or other modifications regarding the ostomy shape can alter the peristomal area, resulting in creases and deep folds, bulging and inward/outward body profiles. An irregular peristomal area and ostomy shape can lead to a suboptimal fit between the ostomy product(s) and the surrounding skin, increasing the likelihood of leakage and PSCs [9, 13, 15, 16]. Consequently, regular follow-ups with a stoma care nurse are crucial for adjusting the ostomy products for a better fit or switching to more appropriate alternatives, and this process takes time [5, 12, 13, 15, 33]. This significance was underscored by a clinical study conducted in Sweden, which demonstrated that regular follow-ups by a stoma care nurse in the first year after ostomy creation reduced the occurrence of PSCs notably [24]. Future research could explore the impact of

TABLE 6 | Ostomy product usage in the first year after ostomy creation.

	Colostomy	Ileostomy	Total
	(*n* = 166)	(*n* = 74)	(*n* = 240)
Number of persons per specific type of starting baseplate, *n* (%)			
Flat	143 (86.1%)	49 (66.2%)	192 (80.0%)
Convex	23 (13.9%)	25 (33.8%)	48 (20.0%)
Number of persons switching starting ostomy baseplate shape, *n* (%)			
Switch of baseplate type	56 (33.7%)	33 (44.6%)	89 (37.1%)
When starting with a flat baseplate[a]	40 out of 144 (27.8%)	26 out of 45 (57.8%)	66 out of 189 (34.9%)
When starting with a convex baseplate[a]	7 out of 22 (31.8%)	1 out of 29 (3.4%)	8 out of 51 (15.7%)
Days to switch, mean (SD)	89.5 (92.2)	60.2 (75.3)	78.6 (87.1)
Number of persons per specific type of ostomy bag, *n* (%)			
1-piece	116 (69.9%)	51 (68.9%)	167 (69.6%)
2-piece	50 (30.1%)	23 (31.1%)	73 (30.4%)
Change of ostomy bag type	44 (26.5%)	17 (23.0%)	61 (25.4%)
Days to switch, mean (SD)	56.3 (55.0)	46.2 (39.0)	53.5 (50.9)
Number of persons using supporting products, *n* (%)			
0 supporting product	2 (1.2%)	0 (0.0%)	2 (0.8%)
1 supporting products	12 (7.2%)	1 (1.4%)	13 (5.4%)
2 supporting products	45 (27.1%)	5 (6.8%)	50 (20.8%)
3 supporting products	44 (26.5%)	27 (36.5%)	71 (29.6%)
4 supporting products	50 (30.1%)	30 (40.5%)	80 (33.3%)
5 supporting products	11 (6.6%)	10 (13.5%)	21 (8.8%)
6+ supporting products	2 (1.2%)	1 (1.4%)	3 (1.3%)
Number of supporting products per person			
Among all persons, mean (SD)	3.02 (1.16)	3.62 (0.90)	3.20 (1.12)
Among persons experiencing episodes of both leakage and PSCs, mean (SD) and median (min;max)	3.46 (1.10) 4.0 (0;5) *n* = 28	3.88 (0.91) 4.0 (2;6) *n* = 32	3.68 (1.02) 4.0 (0;6) *n* = 60

Note: Results were based on data from Swedish health registries unless marked with [a], which were based on data from medical charts.
Abbreviations: max: maximum; min: minimum; PSCs: peristomal skin complications; SD: standard deviation.

pre- and post-operative patient education programmes and standardised follow-up protocols on the outcomes and costs related to leakage and peristomal skin complications. Additionally, investigating how medical provider education, such as clinician qualifications, may influence outcomes and costs is also recommended.

A convex baseplate provides support for the ostomy, preventing it from lying flush to the skin or retracting (Carlsson 2016). It can also compensate for an irregular peristomal area [24, 34–36]. Compared with a flat baseplate, the convexity decreased the risk of leakage episodes in previous studies [26, 37]. Our study showed that the majority of persons started using a flat baseplate. However, of those who initially used a flat baseplate, more than half of the persons with an ileostomy and around one-third of those with a colostomy switched to a convex baseplate within the first year following surgery. Conversely, among those who started on a convex baseplate, only one person with an ileostomy switched to a flat baseplate, while this was the case for approximately one-third of those with a colostomy. We have previously observed that persons who are challenged by leakage issues often benefit from switching to a convex baseplate [15]. To counteract an imperfectly fitting ostomy product, persons with an ostomy will often need more supporting products, such as rings/seals, paste, tape and belts [10, 15, 16, 23]. Our results confirm this, as the number of supporting products increased with increasing episodes of leakage and PSCs.

In this study, the cost of ostomy products was highest for persons with a colostomy, while the cost of supporting products was highest for those with an ileostomy, which is consistent with our

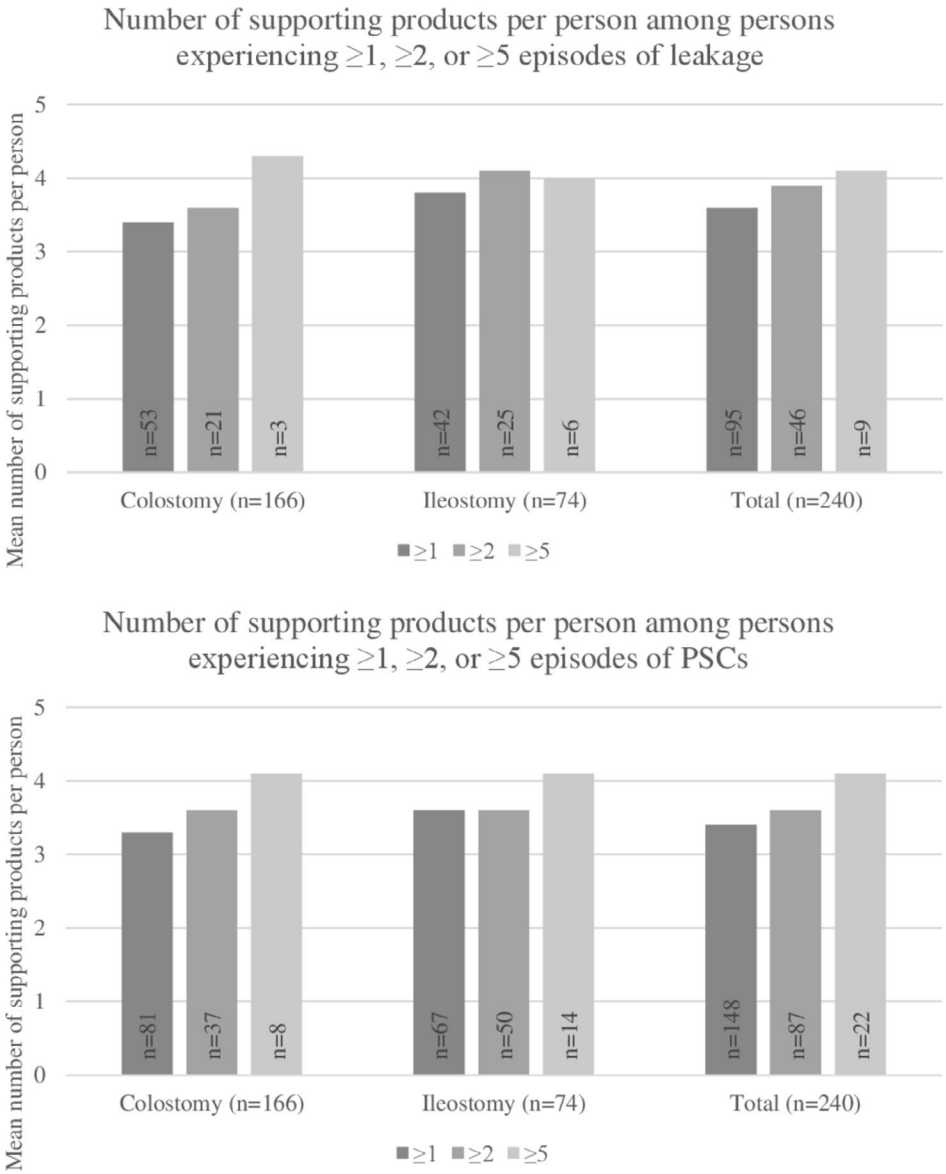

FIGURE 2 | Number of supporting products in the first year after ostomy creation among persons experiencing leakage and/or PSCs according to the frequency of these issues. PSCs, peristomal skin complications. Results were based on data from medical charts. Please refer to Table S3 for values of mean, standard deviation, median, as well as minimum and maximum.

previous nationwide registry study [22]. Additionally, the registry study highlighted that, although the cost of supporting products peaked in the first year after ostomy creation, it remained almost constant for up to 10 years thereafter [22].

4.1 | Strengths and Limitations

Our study has several advantages. Chart reviews use real-world data reflecting reality. The information within the charts is routinely recorded, often in detail, and readily accessible. This approach facilitates the study of conditions that are not captured by registries. Also, an important strength was the possibility of linking a person's data from the medical charts with the same person's data from national registries. Data sets based on retrospective medical charts also have limitations. The medical charts are primarily used for clinical practice and are generally not intended for research purposes. It may vary how data have been recorded in the chart, limiting the extraction and interpretation of the data. Additionally, some charts may be incomplete, resulting in missing data. BMI and abdominal obesity were not explicitly recorded in the medical charts. Factors that influence the occurrence of leakage, PSCs and the person's ability to manage the ostomy were not included in the present study. A relatively small number of participating sites and a selected population visiting a stoma care nurse may limit the extrapolation of the results to the entire population. Generalisation may be limited to similar populations and countries with healthcare systems resembling those in European countries, where universal access to basic healthcare services is available. Despite these limitations, the study provides new and detailed evidence about

TABLE 7 | Costs of ostomy products per person in the first year after ostomy creation.

	Colostomy ($n = 166$)	Ileostomy ($n = 74$)	Total ($n = 240$)
Baseplates (1000 SEK), mean (SD)	20.1 (9.9)	16.1 (9.1)	18.9 (9.8)
Bags (1000 SEK), mean (SD)	20.7 (10.2)	16.3 (9.6)	19.3 (10.2)
Supporting products (1000 SEK), mean (SD)	3.9 (4.3)	9.2 (7.9)	5.6 (6.2)
Total (1000 SEK), mean (SD)	44.7 (21.8)	41.6 (23.6)	43.7 (22.3)

Note: Results were based on data from Swedish health registries. Costs were recorded by flat/concave/convex plates, 1−/2-piece bags, and 8 categories of supporting products (Table S1).
Abbreviations: SD: standard deviation; SEK: Swedish krona.

ostomy-related challenges, which may complement existing data from Swedish registries.

5 | Conclusion

Persons in Sweden living with an ostomy face challenges, such as leakage and PSCs, during the first year after ostomy formation. This study revealed that 38.8% of persons visiting the stoma care nurse had experienced at least one episode of leakage, and 60.0% at least one episode of PSCs within this timeframe. Persons undergoing acute surgery, those with a high ASA classification, and females experienced higher rates of leakage, PSCs, and stoma care nurse visits. Despite meeting the recommended number of visits to the stoma care nurse on average, there was a significant variation. Those experiencing leakage and PSCs required more frequent visits and used more ostomy supporting products, which could result in higher costs for society. This suggests that it is important to prevent leakage and PSC through guidance from the stoma care nurse and supporting the use of appropriate ostomy appliances. A patient-tailored approach based on risk factors, such as surgery type, ASA class, and sex, could potentially reduce complications and healthcare resource utilisation, including stoma care nurse visits. High variability in results further underscores the importance of personalised care. Notably, data on leakage, PSCs and visits to stoma care nurses, which serve as significant quality indicators for outcomes for persons with an ostomy, are not captured in any of the Swedish health registries. Therefore, this chart review provides important information complementing registry studies, adding clarity to the understanding of the clinical and economic burden of living with an ostomy.

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Conflicts of Interest

Eva I. Persson: Registered nurse, senior lecturer, and associate professor, Department of Health Sciences, Faculty of Medicine, Lund University, Sweden. Her contribution to this study was funded by Coloplast. Annabelle Forsmark: Employee of PharmaLex, Sweden, which received consulting fees from Coloplast for the contribution to this study. Gina Scheffel and Catarina Sternhufvud: Employees of Coloplast AB, Sweden. Eva Carlsson: Stoma care nurse, Department of Surgery, Sahlgrenska University Hospital and senior lecturer and associate professor, Institute of Health and Care Sciences, University of Gothenburg, Sweden. Her contribution to this study was funded by Coloplast. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Data Availability Statement

The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.