



A Prospective Cohort Study of Stoma Complications in the Community

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Abstract

Objectives: To clarify the prevalence and costs of Peristomal Skin Complications (PSC) suffered by patients with a stoma in the community, identify risk factors for such complications, and determine if a specialist nurse led intervention programme reduces stoma associated healthcare costs.

Materials and Methods: Ostomate from 179 primary care practices was invited to attend a review from a stoma care specialist nurse between June 2016 and February 2018, recording the prevalence of complications. Interventions included: clinical advice, stoma product advice and changes. To determine which factors were more likely to increase the risk of PSC; a binary logistic regression was performed. An established cost analysis model was used to quantify the annual cost of identifying and treating PSC.

Results: Initial visits were conducted with 1968 ostomates over 21 months. PSC were identified in 24% of the patients (n=469). Comparative risk factors for PSC were; a recently formed stoma (<6 months), an ileostomy rather than a colostomy and inflammatory bowel disease rather than bowel cancer. Annual mean cost of identifying and treating PSC was £521/patient. The estimated total annual cost savings for the cohort from avoided NHS appointments was £31/patient. A 10% decrease in stoma products used corresponded to £229/patient annual cost saving.

Conclusion: Stoma patients currently experience a range of complications which can last several years after stoma formation. Clinical review by nurse specialists is associated with significant cost savings, including reductions in unplanned visits with healthcare specialists and decrease in products used.

Keywords: Stoma; Ostomate; Skin complications; Ileostomy; Colostomy

Introduction

In the year 2017/18, 21,015 stomas were formed in patients in England, with 6765 (32%) of them planned as temporary [1]. Nonetheless, the burden on the patient and the healthcare system is significant. Having a stoma incurs direct costs in terms of stoma appliances and accessories and is associated with poorer quality of life [2-4]. There is a high rate of complications among people with a stoma both in the short and long term, with rates as high as 82% reported within the first year after surgery [5,6]. Early stoma complications are well recognised in secondary care as ostomates are twice as likely as patients with a primary bowel anastomosis to be readmitted within 30 days of surgery [7]. However, stoma complications can occur at any point and even patients with a well-established stoma can experience complications, particularly peristomal skin complications [8]. There are conflicting opinions about the type of stoma which is at greatest risk of complications. Having an ileostomy has been shown to represent a 2.3-fold increased risk compared to a colostomy in long term ostomates in a Danish community study [9]. However, others have identified a colostomy as a greater risk, particularly in the early post-operative period [10]. Other risk factors include: a short stoma length, patients with a higher body mass index, patients having undergone emergency surgery and stomas formed without preoperative site marking [10-12]. Appropriate preoperative stoma site marking not only reduces the incidence of stoma complications but improves health related quality of life [13]. It is standard practice in the UK that patients in hospital with a newly formed stoma will be reviewed by specialist Stoma Care Nurses (SCN) and contact information is shared or a follow up arranged in the community on discharge. While there are local protocols, there is no national formal pathway for a routine stoma review, no national guidelines and, in many cases; the review

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is performed at the patient's request rather than routinely. However, patients' perceptions of issues such as poor skin health can be limited. Only 38% of patients with a diagnosed Peristomal Skin Complication (PSC) had recognised the skin issue as a problem requiring medical intervention [9]. Therefore, relying on patients to seek stoma care or medical attention will disadvantage those who are less well informed and unaware of how a normal stoma should function. The proportion of patients who seek treatment may be even smaller, reported in as low as 16% [11]. In addition, stoma morphology changes and matures following discharge from hospital including becoming more prolapsed or retracted. As a result, the appliances prescribed to patients on discharge from hospital may not be the most appropriate for optimum long-term function. The benefits of a specialist SCN-led review and intervention in the community following stoma formation, which has not been previously studied, may be effective as specific stoma related patient education preoperatively has been shown to improve quality of life and decrease early complication rates [14,15]. Existing large UK community data sets provide the opportunity to explore SCN practices using secondary analyses. The purpose of this study was to investigate the benefit of a specialist SCN-led review of ostomates, thus informing future practice guidelines to consider clinical review of this population. In addition, this study seeks to: 1. determine the prevalence and costs of PSC suffered by ostomates in the community; 2. identify risk factors for PSC, and; 3. investigate if a specialist SCN-led intervention programme confers patient reported benefits and cost savings.

Materials and Methods

General Practitioner (GP) practices from 27 Clinical Commissioning Groups (CCGs) and 1 Health Board (Belfast) participated in clinical reviews over 21 months between June 2016 and February 2018. Deprivation scores for the CCGs included were identified from Public Health England [16]. Practices were identified through a selection process which involved assessing the spend on stoma supporting products for each practice, where a high practice spend suggested that ostomates were experiencing issues with their stoma and could potentially benefit from clinical review. Specialist SCNs were provided by Coloplast. There were nine members of the Care Quality Commission (CQC) accredited nursing team, all of whom were fully trained and adhered to the Royal College of Nursing and Nursing and Midwifery Council guidance. A Data Protection agreement and Service Level Agreement was signed with each practice, and all data collected were anonymised. All ostomates were invited for a SCN-led review via letter from the GP practice. Patient participation in the study was estimated at 45%. Patients were sent a pre-visit questionnaire to identify their current prescribed products, and which types and numbers kept in reserve at home. During the clinic review, the prevalence of complications was identified through a pre specified pro forma including basic demographics, details of stoma type and issues experienced with the stoma. Interventions carried out at the SCN review included clinical advice, stoma product advice and product change. A patient satisfaction survey was used to record whether the review was deemed beneficial and if it likely reduced NHS resources by avoiding visits to GPs, hospital or community SCNs and Emergency Departments (ED). Further clinical reviews were offered to ostomates as required. A cost analysis was used to quantify the annual cost of treating PSC and estimate cost savings. An established cost model was used to calculate an average cost of treating a PSC episode [2]. In the model, PSC treatment costs were estimated for the different severities of five different underlying

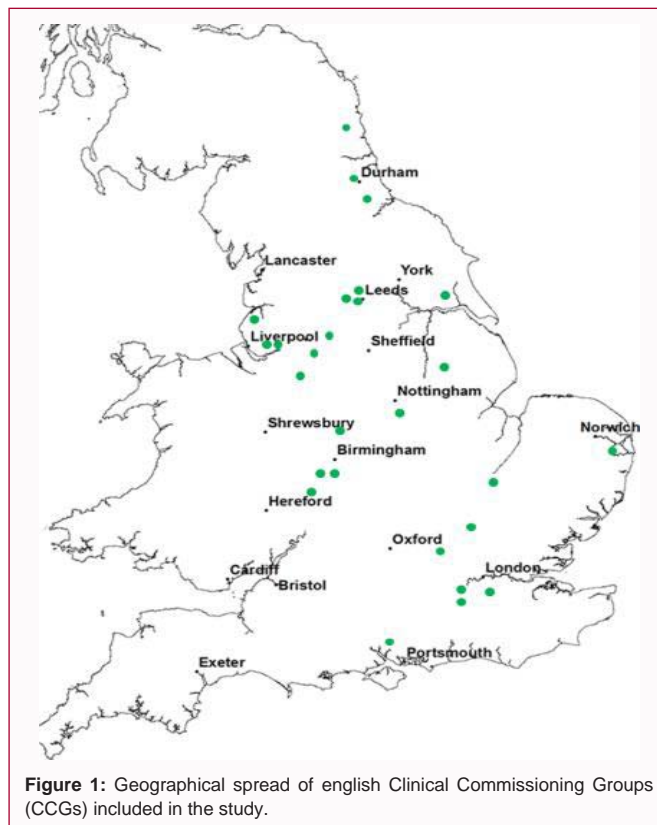


Figure 1: Geographical spread of english Clinical Commissioning Groups (CCGs) included in the study.

skin conditions such as irritant contact dermatitis, based on global treatment pathways. The costs were based on an assumption of 7 weeks of treatment, derived from findings that a significant clinical improvement in PSC is expected within 6 to 7 weeks [17]. The treatment pathways for each condition and corresponding unit costs were updated to reflect current UK practice and prices. The annual expected cost of identifying and treating PSC was estimated for those with PSC (n=469) and for the whole sample (those with and without PSC, n=1968), assuming a fixed prevalence rate of recurring PSC during the year. To calculate potential cost savings from reduced activity in the NHS, patient reported avoidance of healthcare activity (from the patient satisfaction survey) was used combined with NHS reference unit costs for a SCN appointment (£127), GP appointment (£37) and ED visit (£202) [18,19]. Estimated savings from changed product usage were based on the cost of the individual products assigned by the nurse when reviewing the patients' product list. Patient reported sore skin was used as a measure of PSC. To determine which factors were more likely to increase the risk of PSC a binary logistic regression was performed with PSC as the dependent variable. Data analysis was conducted using Microsoft Excel version 2010 and IBM SPSS Statistics version 22.

Results

The geographical spread of the 27 English CCGs is shown in Figure 1. The mean deprivation score for the CCGs was 20.1, which is comparable with the mean score for England of 21.8 [16]. A total of 1968 patients attended an initial visit with a SCN specialist. The patient demographics (Table 1) show a median age of 72 years (62 to 80 interquartile range) with a slight male preponderance (n=1065, 54%). Included were; 631 patients with an ileostomy (32%), 645 with a colostomy (33%) and 216 with a urostomy (11%). Most stomas were formed for benign disease (60%), although there was a cancer

Table 1: Patient demographics.

		Median (interquartile range)
Age (years)		72 (62-80) n (%)
Gender	Male	1065 (54%)
	Female	903 (46%)
Duration of stoma	Less than 6 months	28 (1%)
	6 to 12 months	103 (5%)
	1 to 5 years	426 (22%)
	More than 5 years	920 (47%)
	Missing data	491 (25%)
Type of stoma	Ileostomy	631 (32%)
	Colostomy	645 (33%)
	Urostomy	216 (11%)
	Unsure	5 (<1%)
	Missing data	471 (24%)
Reason for stoma	Benign	1176 (60%)
	Colitis	282
	Crohn's disease	116
	Diverticular disease	125
	Other (including functional problems)	221
	Unknown	432
	Cancer	792 (40%)
	Bowel cancer	483
	Bladder cancer	196
	Rectal cancer	113
Last stoma review	Within the last month	44 (2%)
	1 to 6 months ago	200 (10%)
	6 to 12 months ago	174 (9%)
	More than a year ago	210 (11%)
	More than 2 years ago	869 (44%)
	Missing data	471 (24%)

diagnosis for 40% (n= 792) (Table 1). Most patients were long term ostomates with nearly half having had their stoma formed more than 5 years ago (n= 920, 47%). The number of patients known to the community stoma team was 266(14%) and more than half of patients had not had a stoma review for more than 12 months (n=1079, 55%). Overall 92% of patients were satisfied with the specialist SCN-led review with reasons including improved awareness of their condition, psychological support and alleviation of suffering (Table 2). The prevalence of complications or issues reported by patients is shown in Table 3. A mean of 0.9 general issues were identified per patient. Specialist SCN-led reviews led to 4266 interventions, with a mean of 2.17 interventions per patient. Patient reported PSC were found in 469 patients (24%). Type of stoma, reason for the stoma formation and the duration of the stoma were all found to be significant risk factors for PSC development (Table 4). An ileostomy was almost 2-fold more likely to be associated with PSC than a colostomy. Having a stoma formed for bowel cancer was least likely to be associated with PSC where as Colitis and Crohn's disease were associated with a more than 2-fold likelihood of PSC. The risk of having PSC was greatest in the group having a stoma for less than 6 months (100% PSC out of n = 26) and the risk increased slightly between the 6-12-monthgroup

Table 2: Patient reported benefits.

Benefits of stoma review	n (%)
Improved awareness of their condition	666 (34%)
Psychological support	524 (27%)
Advice on medication	283 (14%)
Alleviation of suffering	282 (14%)
No additional review benefits	150 (8%)
Image counseling	9 (<1%)

Table 3: Patient reported stoma issues or complications.

Problem	n (%)
Leakage	484 (25%)
Sore skin	469 (24%)
Hernia	248 (13%)
Social concerns	164 (8%)
Pancaking	95 (5%)
Ballooning	87 (4%)
Granuloma	71(4%)
Other	67 (3%)
Prolapse	23 (1%)
High output	16 (1%)
Ulceration	5 (<1%)
Stoma stenosis	2 (<1%)
Muco-cutaneous separation	0 (<1%)

(6.3% PSC out of 96) and the 1-5-year duration group (14.3% PSC out of 363), although after 5 years the likelihood of a PSC decreased (0% PSC out of 827). The average cost of treating a PSC episode was £240 per patient (treatment length 7 weeks). Based on recurring PSC, the expected annual mean cost per patient of identifying and treating PSC for only those with PSC (n=469) was £1781 compared to £521 per patient in the whole cohort (n=1968). Further, with 1968 ostomates included in the study, the overall expected annual mean cost of identifying and treating PSC was £1,025,667. There was a reduction in use of NHS resources in 75% of patients through reducing wasted products and avoiding unnecessary appointments with the GP or ED. The expected mean annual cost saving for the entire cohort from avoided SCN appointments was £53,523, £6618 for GP appointments and £346 for ED visits, resulting in a total of £60,487, which averages at £31 per patient per year. Furthermore, by reviewing the patients' product usage, 948 products were stopped, 508 products were changed, and 209 new products added. Waste was high with 9% of patients having inappropriate products, 8% over ordering leading to stock piling and 5% with products not being used. A 10% decrease in product costs (£191 reduced to £172 average monthly spend per patient) was seen, corresponding to £450,106 as an annual cost saving in the study group. This translates to product cost savings of £229 per patient annually.

Discussion

The aim of this study was to identify the prevalence of stoma complications in the NHS in order to highlight potential deficiencies in community stoma care provision, areas for improvement, and the associated cost-savings. This study identified PSC among 24% of the ostomates with an ileostomy having a significantly increased risk of 1.914 compared to colostomy. This is similar to a 2.3-fold increase

Table 4: Odds of developing sore skin.

Variable	Risk factor	N	No sore skin n (%)	Sore skin n (%)	Odds (95% CI)	p
Reason for stoma formation	Bowel cancer	388	376 (96.9%)	12 (3.1%)		
	Bladder cancer	170	167 (98.2%)	3 (1.8%)	1.122 (0.45-2.79)	0.804
	Other	204	202 (99%)	2 (1%)	1.572 (1.03-2.4)	0.036*
	Diverticular disease	106	102 (96.2%)	4 (3.8%)	1.576 (0.95-2.62)	0.079
	Rectal cancer	83	82 (98.8%)	1 (1.2%)	2.046 (1.18-3.55)	0.011*
	Colitis	252	212 (84.1%)	40 (15.9%)	2.175 (1.42-3.34)	0.001*
	Crohn's disease	109	87 (79.8%)	22 (20.2%)	2.738 (1.66-4.52)	0.001*
Duration of stoma	Less than 6 months	26	0 (0%)	26 (100%)		
	6-12 months	96	90 (93.8%)	6 (6.3%)	0.203 (0.12-0.34)	0.001*
	1-5 years	363	311 (85.7%)	52 (14.3%)	0.244 (0.17-0.34)	0.001*
	More than 5 years	827	827 (100%)	0 (0%)	0.144 (0.11-0.2)	0.001*
Type of stoma	Colostomy	550	542 (98.5%)	8 (1.5%)		
	Urostomy	198	194 (98%)	4 (2%)	1.356 (0.59-3.1)	0.469
	Ileostomy	564	492 (87.2%)	72 (12.8%)	1.914 (1.37-2.68)	0.001*

*Significantly different from first category in each variable; P<0.05.

found previously in patients with stomas for a mean of 8 years, although a higher rate of 45% of ostomates having PSC was reported. The difference between rates of PSC could be attributed to different methodology, with the current study using patient reported data rather than healthcare identification. Also, differences in prevalence of PSC may be due to different patient cohorts. The most likely explanation for ileostomates being at greatest risk of PSC is the liquid stoma effluent coming into contact with the skin on a regular basis and the need for frequent appliance changes. This was reported in Danish patients, with greatest risk of skin problems for those with an ileostomy, those suffering frequent leakage, and obese patients [11]. The indication for stoma formation was also a significant factor in determining the risk of PSC with the highest risk being seen in patients with inflammatory bowel disease, particularly Crohn's disease. Such patients are more likely to have an ileostomy and to suffer from complications due to high output, leakage and peristomal ulceration. This study found that the risk of PSC was greatest within the first 6 months of stoma formation, where 100% of the 26 patients in this group had a PSC (Table 4). Although other studies have different follow-up periods, high rates have been found previously including 63% within a 3 month follow-up in a small United States study, and 82% of patients had stoma complications, most commonly PSC and bag leakage, within 1 year of stoma formation [5,6]. Problematic stomas in the early post-operative period are associated with longer hospital stays and increased reliance on community stoma teams [10]. The 26 patients in this study may be an under-representation with people not reporting a problematic stoma if they felt another or different stoma review was not required within the 6 months of stoma formation. For those patients who do not have an early complication, high quality community stoma care is still vital to identify patients before problems develop. Ostomates are generally ill-informed about skin health. Participants in this study were approached rather than self-presenting, possibly as ostomates accept PSC as "part and parcel" of having a stoma rather than seeking help. In the past, only 38% of patients with a diagnosed PSC had recognized the skin issue as a problem, and only 53% of participants were aware of their skin issues suggesting that patient-reported PSC is likely to be low [9,20].

Published literature on healthcare professional assessed PSC report a prevalence rate between 45% and 61%, indicating that the true burden of PSC may be understated in this study [9,17]. Also, the true number of ostomates with PSC may be higher as study participation was estimated at 45%. SCN review in this study has demonstrated that there may be sub-optimal management of stoma complications in the community, particularly for PSC. Regular review would allow a point of contact for ostomates, enabling better management of ongoing or new stoma related complications, but may also have other long term benefits. Improved awareness of their condition was stated by 34% of the study population after their SCN review. Future care should involve good patient education, striving to reduce the impact of stoma related complications. Structured educational activities aimed at increasing knowledge have been shown to improve quality of life among ostomates [14]. Not only would such a service provide much needed information for ostomates, but would also allow a contact session whereby problems could be identified and group sessions arranged to provide an opportunity for peer support. Enhanced recovery programmes, laparoscopic surgery and NHS drives for early discharge see patients transferred to the community sooner than previously and therefore vigilance and patient knowledge is essential. But patients with long term stomas were not without issues. Some 14% of ostomates with a stoma formed between 1 and 5 years ago had PSC and therefore an ongoing relationship with community stoma care is essential even if there are no early complications. Possible explanations include weight change or hernia development, worsening eyesight or dexterity among older patients, with the consequences being poor appliance fit leading to leakage and peristomal skin complications. Patients who had no stoma review for 2 years or more totalled 44% of the study population. Despite it being routine practice for patients to be discharged from hospital with contact details for ongoing stoma care, the number of patients known to the community stoma team was small (n=266, 14%) and more than half of patients had no stoma review for more than 12 months (n=1079, 55%). This study did not account for follow up with hospital teams and there may have been some patients receiving care outside of the community setting. However, the large number of patients seemingly out of touch with

the community service implies a missed opportunity for a better level of care and cost for the provider. This also includes nurse-led interventions targeting waste and although most patients were using an appropriate product (76%), nurses managed to reduce ordering of unnecessary stock. The financial benefit of the nurse-led review was significant with £450,106 as an annual cost saving in the study group. To roll out a regular stoma review service there would be staffing and logistical costs, but these would likely be mitigated by such a cost saving.

Limitations

Participation uptake of 45% with a potential bias from the more motivated patients may underestimate the true prevalence of PSC. The wide geographical spread of participating CCGs and comparable deprivation scores to England suggests that the results of this study are representative of the English NHS. However, Wales and Scotland were not included and only one practice from Northern Ireland was included. The SCN-led review was funded by Coloplast; however, the product changes were made to best manage the patients' individual situation and were not limited to Coloplast products. The overall result of the SCN-led reviews cut down on product usage therefore any industry bias was minimal. The expected annual costs to the NHS of identifying and treating PSC were based on health economic calculations, assuming that patients experience recurring PSC. With limited evidence on the true frequency of PSC in a given year for an ostomate, it is difficult to assess the exact rate and the extent of the problem. Additionally, a validated skin tool was not used to identify the severity of PSC during the reviews, thus potentially reducing consistency in terms of the definition of sore skin and severity across SCNs. The use of a skin tool would allow for better demonstration of the level of improvement or change of PSC.

Conclusion

PSC is an important and prevalent issue which occurs more frequently with a newly formed stoma. Community and hospital teams need to ensure better access to high quality stoma care and establish regular reviews for long term ostomates. A review of ostomates led by a specialist SCN can lead to cost savings including, a reduction in resource utilisation costs and product costs.

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