



Long distance to hospital is not a risk factor for non-reversal of a defunctioning stoma

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Abstract

Purpose To see if road distance to hospital influences stoma reversal rate, time from index operation to stoma reversal, and occurrence of permanent stoma.

Methods Data from all diagnosed cases of rectal cancer from three counties in northern Sweden were extracted from the Swedish Rectal Cancer Registry. The three counties are sparsely populated, with a population density roughly one fifth the average density in Sweden. Distances to nearest, operating, and largest hospital were obtained using Google Maps™. Matched data on socioeconomic variables were retrieved from Statistics Sweden.

Results In univariate logistic regression analysis, patients living closer to the operating hospital had a higher likelihood of non-reversal than those living farther away (OR 0.3; 95% CI 0.12–0.76). However, no difference was seen in the multivariate analysis. Of the 717 cases included, 54% received a permanent stoma and 38% a defunctioning stoma at index surgery. The reversal rate of a defunctioning stoma was 83%. At follow-up, 61% still had a stoma, 89% of these were permanent, and 11% non-reversed defunctioning stomas. Median time to stoma reversal was 287 days (82–1557 days). Of all 227 stoma reversals, 77% were done more than 6 months after index surgery.

Conclusions Longer distance to hospital is not a risk factor for non-reversal of a defunctioning stoma. Only 23% had their defunctioning stoma reversed within 6 months after index surgery. Future studies aiming to determine reversal rate need to extend their follow-up time in order to receive accurate results.

Keywords Rectal cancer · Defunctioning stoma · Permanent stoma · Stoma reversal · Distance · Rural

Introduction

A defunctioning stoma reduces the risk for symptomatic anastomotic leakage in patients undergoing anterior resection (AR) for rectal cancer [1]. Despite the initial intention of restoring bowel continuity, previous studies have shown that a significant proportion of defunctioning stomas will become permanent [2–6]. Anastomotic leakage is the best studied risk factor for non-reversal, but high age and advanced tumor stage is also described [6–9]. Studies from countries with a social structure similar to Sweden have indicated that socioeconomic factors may also affect stoma reversal rates [9–11]. Road

distance between home and hospital has not been studied as a risk factor for non-reversal.

From the European perspective, Sweden is a sparsely populated country, particularly the three northernmost counties, with a density of 2.5–5 inhabitants per square kilometer compared to 24.5 for the country as a whole, and 420 for England [12, 13]. This low density results in a longer mean distance to hospital; a factor that has been shown to be associated with advanced staged disease at diagnosis [14]. Rural areas in one of the counties included have a higher prevalence of diabetes and cardiovascular disease compared to the urban areas [15]. The proportion of old people with a low level of education is also higher in the rural areas of northern Sweden compared to the general population [12]. Defunctioning stoma is associated with impaired social functioning such as distorted body image and less sexual interest. When reversed, these effects seem to be reduced and the global quality of life (QoL) seems to improve [16]. Patients with a permanent stoma have generally been found to have a lower QoL but also problems with pain,

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skin excoriation, and leakage [17, 18]. Failure to reverse a defunctioning ileostomy after rectal cancer surgery is counter to the fundamental purpose of preserving the sphincter at the index operation.

In Sweden, all diagnosed cases of rectal cancer are reported to The Swedish Rectal Cancer Registry (SRCR) [19]. The registry is regularly cross matched against The National Cancer Registry to which clinicians and pathologists are obliged to report. Completeness of the SRCR for the years 2007–2011 was 99% and data are considered to be population-based [20].

Since the Swedish health care system is government-funded, and all taxpayers contribute to the health care system, it is considered important to investigate possible geographical inequalities between patient groups. This is also encouraged by both the government and the National Board of Health and Welfare [21, 22].

The aim of this study was to assess whether road distance to the hospital has an effect on the outcomes: stoma reversal rate, time from index operation to stoma reversal, and occurrence of permanent stoma. Our hypothesis was that a longer distance to hospital affects these outcomes negatively.

Method

Patients diagnosed with rectal cancer in the Northern (Västerbotten, Norrbotten, and Jämtland Counties) part of Sweden between 1st January 2007 and 31st December 2014 were identified using the SRCR. Details concerning patient characteristics, pathological assessment, surgical details, stoma, and possible use of stent were obtained. In the regions included, almost all elective rectal cancer surgery was performed at the largest hospital in each region. Resection surgery performed at any of the smaller hospitals could, for the time period, be considered as an exception. The follow-up and stoma reversal procedure, however, could very well be performed by one of the smaller local hospital included.

Stomas were classified as either permanent after abdominoperineal resection (APR) and Hartmann's procedure (HP), or protective defunctioning after most cases of anterior resection (AR). When answers in the registry stated "No" to the question "permanent stoma after HP/APR", "Yes" in "permanent stoma after AR", or data missing, the medical records were used to validate that information. Our original intention was to classify a defunctioning stoma as being permanent if not reversed within 18 months, but data from medical records showed reversals beyond that time line, so the decision was made not to use a predefined time limit. Delayed reversal was defined as > 6 months (182 days). This time was chosen since it was the median time to reversal in a larger study in Sweden that included data from around the same period [9]. That study, however, did not assess the effect of distance.

Registry data available for this study does not specify whether the defunctioning stoma was performed as a loop ileostomy or a loop colostomy. However, in the regions included, the routine when performing AR is to fashion a loop ileostomy. This statement is strengthened by results from Holmgren et al., who performed a register-based study in the Northern health care region in Sweden 2007–2013 [23]. Their study comprised all diagnosed cases of rectal cancer patients in all three regions included in this study, but also the county of Västernorrland. They reported 38 loop colostomies out of totally 274 defunctioning stomas. Therefore, it is safe to say that the vast majority of defunctioning stomas reported in this study consists of loop ileostomies.

To achieve the aims of this study, patients receiving a permanent stoma without resection of the tumor were considered palliative and therefore excluded. All types of resection surgery that could possibly involve a stoma were included. Endoscopic polypectomy, transanal endoscopic microsurgery (TEM), local excision, and stent were therefore excluded.

To assure that no defunctioning stoma was lost to inclusion, all cases where registry data stated that a defunctioning measure was employed were scrutinized. A preoperative defunctioning stoma not followed by tumor resection was considered palliative and thus deemed not to be defunctioning for the purposes of this study, based on the same argument that permanent stomas were not included.

In all cases where a defunctioning stoma had been placed, the medical records were scrutinized for information regarding if and when the stoma was reversed. When the medical record contradicted registry data stating "Yes" in defunctioning stoma (e.g., anastomotic leakage > stoma reversal and placement of permanent colostomy), information from the operation notes was taken as being correct and data were corrected accordingly.

Addresses were retrieved from the medical record in order to estimate road distances between the patient's home and the hospitals considered in the study. Dates for index surgery and, where applicable, stoma reversal were also retrieved from the medical records. Data from medical records in Norrbotten and Västerbotten counties were obtained during August 2017, and from Jämtland county between April and May 2018 resulting in follow-up times of at least 32 months for patients operated towards the end of 2014.

Distances from the patient's home and the catchment (or nearest) hospital, the operating hospital, and the largest hospital in the region were calculated and grouped. All distances were obtained using Google Maps™.

All data were matched against data from Statistics Sweden from which information on income, marital status, Swedish/foreign background, and level of education was obtained. Prior to analysis, grouping was performed for some of the variables included in the regression analysis. This was done

to facilitate the illustration of their impact on the outcomes specified in the aim.

Level of education was grouped into three categories: no high school diploma, high school graduate, and college graduate. Income was grouped into three categories based on quartiles: the lowest quartile, highest quartile, and the reference group containing the two intermediate quartiles. Age quartiles were grouped in the same manner. Grouping of these three variables was based on the assumption of a non-linear relationship where the older, poorer, and lower educated had a different outcome to that of their opposites. Marital status was divided between married or living in partnership, and unmarried. “Unmarried” included divorced, never married, or widow/widower. Ethnic background was divided into three groups: born in Sweden of Swedish parents, born in Sweden of non-Swedish parents, and not born in Sweden.

All data on marital status, level of education, ethnic background, and disposable income at the time of diagnosis were matched and retrieved from Statistics Sweden. Disposable income was converted into euros based on the exchange rate on the bank day closest to 31st December for each year [24].

The relationship between distance to hospital and the three outcomes was tested by both linear and logistic regression. In the logistic regression analysis, distance was either grouped into four quartiles, or two groups with the 90th percentile as the cut-off point. Both methods were applied since no previous study has investigated these relationships.

Statistics

Linear and uni- and multivariate logistic regression analyses were used. Comparisons of means in the linear regression analysis were made using *t* test or ANOVA, depending on how many categories there were in the predictor variable. In the multivariate analyses, all variables were entered at the same time (force entry). Prior to the multivariate regression analysis, all parameters were judged regarding their mutual dependence. As a result, only distance to the operating hospital was included, the other distances not included have been described previously. All analyses were performed using STATA version 13.1 (STATACorp LP, College Station, TX, US).

Compliance with ethical standards

Ethics approval of this study was obtained from the Regional Ethics Committee in Umeå (Dnr 2016/155-31). For this type of study, formal consent from each patient is not required. The authors declare that they have no conflicts of interest in this study.

Results

Registry data constituted 1021 cases of rectal cancer. Five double registrations were excluded. Three patients were never treated in regime by the regions specified. When assessing the occurrence of permanent stoma, 717 cases remained for analysis after excluding non-surgical treatment, stent only, endoscopic polypectomy, TEM, local excision, and no tumor resection surgery (Fig. 1).

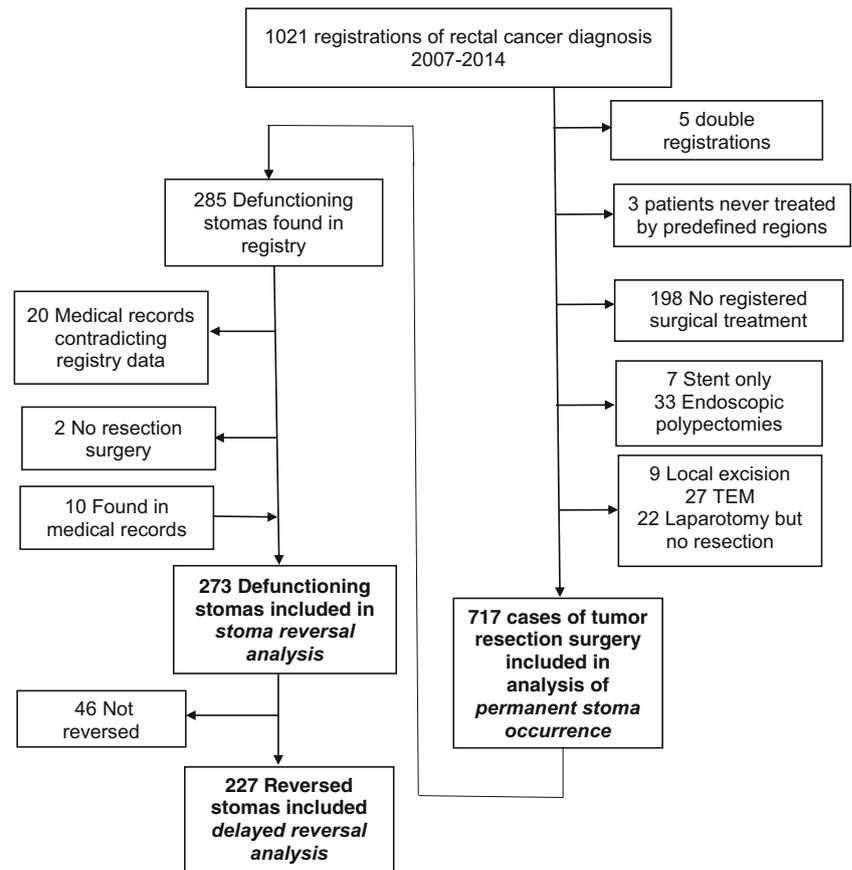
Data from the registry stated that a defunctioning stoma was placed in 285 cases, but after scrutinizing the medical records, 20 of these had received an end colostomy due to surgical complications; these were considered to be permanent. Two cases never had tumor resection surgery and were thus excluded. When analyzing missing data or “No” in the defunctioning stoma column after AR, we found 10 additional cases where a defunctioning stoma was placed but not reported to the registry. After this process, 273 defunctioning stomas were finally included; all but one placed during AR (one case after colectomy and J-pouch). Of these 273 defunctioning stomas, 46 had not been reversed by the end of the study period, leaving 227 for the analysis of delayed stoma reversal (Fig. 1).

Of the 717 cases with tumor resection surgery included, 54% received a permanent stoma, 38% a defunctioning stoma, and 8% no stoma (Fig. 2). The defunctioning stoma reversal rate was 83%. All dates for stoma reversal were identified in the medical records except in one case where only month, year, and admission date for surgery were entered. In that case, the day after admission to hospital was chosen as date of stoma reversal. Seventy-seven percent of stoma reversals were performed more than 6 months after index surgery. Median time to stoma reversal was 9.4 months (287 days), range: 82–1557 days. Seventeen of 227 (7%) reversals were performed more than 18 months (547 days) after index surgery.

In the linear regression analysis, distance to hospital was not a significant factor affecting permanent stoma, non-reversal of a defunctioning stoma or delayed stoma reversal. However, in cases where stoma reversal was delayed, the mean distance to the operating hospital was 102 km compared to 66 km in cases where reversal was not delayed ($p = 0.07$) (Table 1). Among other independent variables tested, only T-stage had a significant relationship to mean distance from hospital in the linear regression model when leaving out factors previously known to be related (e.g., lower level of education in the rural areas). The mean distance to hospital when having a T1 tumor was 22 km, while the mean distance when having a T4 tumor was 51 km. However, this difference was not significant when comparing means using ANOVA ($p = 0.06$).

In the univariate logistic regression analyses, patients living closer (1st quartile) to the operating hospital had a higher likelihood of non-reversal compared to patients living further away (OR 0.30; 95% CI 0.12–0.76). Patients living within the

Fig. 1 Flow chart of included patients. After sorting out double registrations and patient not treated by regions specified, the process of sorting out cases of tumor resection surgery, protecting stomas and reversed stomas were performed. The process is described in detail in first two paragraphs in “Results” section



3rd quartile from the nearest hospital also had a lower likelihood of non-reversal compared to those living closer (OR 3.13; 95% CI 1.16–8.49). These differences, however, were not significant in the multivariate analyses where only metastasized disease and N1-stage significantly increased the likelihood of non-reversal (M1-stage: OR 0.14; 95% CI 0.03–0.57 and N1-stage: OR 0.25; 95% CI 0.08–0.72). Higher T stage had no significant effect on non-reversal. The results showed regional differences, where patients living in Norrbotten county had a lower likelihood of non-reversal in the univariate model (OR 2.37; 95% CI 1.04–5.40) (Table 2). Age, gender, ASA class, and the socioeconomic variables

tested did not have a significant effect on non-reversal. The other two variables describing distance (distance to nearest and largest hospital) were calculated separately in the same multivariate model but no significant effects were revealed.

In the analysis regarding factors possibly determining the proportion of permanent stoma, and delayed stoma reversal, distance to hospital had no significant effect in the univariate regression model. In the analysis of delayed stoma reversal, all three counties had reversal delay in over 70% of cases. Jämtland county had a significantly higher delay rate than Västerbotten county (87.7% vs 70% resp. $p = 0.016$).

Fig. 2 Percentage of patients receiving permanent or defunctioning stoma after tumor resection surgery in northern Sweden 2007–2014

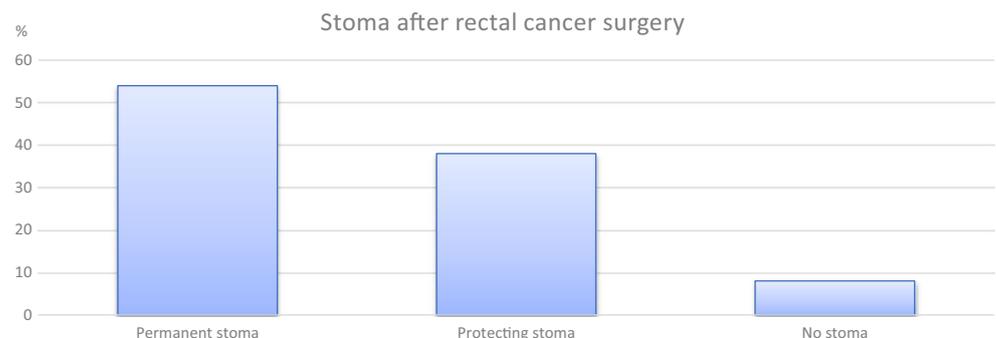


Table 1 Mean distance to hospital as a binary independent variable in a linear regression model for the outcomes; permanent stoma, non-reversal of defunctioning stoma or delayed reversal (> 6 months). *P* values from *t* test

	Nr		Mean distance nearest (catchment) hospital (km)	<i>P</i> value	Mean distance operating hospital (km)	<i>P</i> value	Mean distance largest hospital in county (km)	<i>P</i> value
Permanent stoma <i>n</i> = 717	388	Yes	41.5	0.69	100.6	0.24	93.8	0.18
	329	No	40.0		89.70		85.2	
Mean distance entire group			40.8		95.6		89.9	
Non reversal <i>n</i> = 273	46	Yes	32.0	0.27	79.7	0.47	79.8	0.74
	227	No	40.9		93.7		84.3	
Mean distance entire group			39.4		91.3		83.5	
Delayed reversal <i>n</i> = 227	175	Yes	42.3	0.47	101.9	0.07	86.5	0.47
	52	No	36.4		66.0		76.8	
Mean distance entire group			40.9		93.7		84.3	

Discussion

The major finding in this study was that nearly four of five patients had to wait more than 6 months after index surgery to have their defunctioning stoma reversed. Contrary to the hypothesis proposed in this study, there was no relationship between delay in reversal and distance to the operating hospital. In 2013, Flodeen et al. showed a similar proportion of patients getting a delayed reversal, but their definition of delay was 2 months shorter than that used in this study [8]. Since their study was also carried out in Sweden, this suggests a negative trend with patients waiting longer for reversal of their stoma. The aim of this study was not to investigate the reasons for this delay besides the effect of distance, but Flodeen et al. showed that in more than 50% of cases, delay was caused by the low surgical priority given to this procedure. Other reasons explaining delay in their study included non-surgical complications, anastomotic leakage, and chemotherapy. It is highly unlikely that a major increase in the rate of these factors is responsible for the increasing delay seen in Sweden, supporting the notion that the stoma reversal procedure has been given lower priority in recent years.

Median time to stoma reversal in this study was 9.4 months (287 days) and 77% of stoma reversals were performed more than 6 months after index surgery. A similar study, which also included rectal cancer patients only, reported a median time to reversal of 129 days (range 58–326) [25]. Another, slightly larger study, also assessing reversal rates of defunctioning stoma, reported a corresponding time of 192 days (range 14–865) [26]. Compared to other European countries, the interval to stoma reversal reported in this study is also remarkably longer, with a median time to reversal more than 3 months longer than other studies [16, 27]. This prolonged time period raises a couple of ethical aspects that should be discussed.

First, Herrle et al. showed that a defunctioning stoma had a negative effect on gastrointestinal symptoms and “role functioning” and that these parameters improved significantly after reversal [16]. Given these results, a prolonged interval to stoma reversal causes unnecessary suffering for many patients. Another ethical aspect of this prolonged interval is the presumable effects on number and length of sick leaves. A large proportion of rectal cancer patients is below 67 years of age, the retirement age in Sweden. A retrospective Swedish study reported that about one third (29%) of all patients with a defunctioning ileostomy after AR had at least one episode of dehydration (stoma output > 2000 ml) [28]. Half of these patients were readmitted to hospital and two (2%) patients needed ICU care [28]. Even if no studies exist within this subject, it would be naive to believe that the months of prolonged waiting for reversal for the patients in this study would not render increased sick leave. This in turn could lead to a decreased income for each individual affected, but also decreased tax income to a publicly funded health care system, as that in Sweden.

A commonly used definition of when a defunctioning stoma is defined as permanent is 18 months after index surgery. Many studies, including ours, have been designed using a follow-up period based on this definition. A previous study published by our research group had a follow-up time of 18 months after stoma creation [9]. However, in the present study, 17 of 273 stomas were reversed after 18 months. Pan et al. had a median follow-up time of 29 months [26], and two cases in that study were reversed after that time. Similar studies in the future must consider the possibility of stoma reversal occurring long after the index operation if rates are to be accurate. One strength of this study is that patients operated at the beginning of the study had a very long follow-up thus providing an accurate reversal rate. On the other hand, a

Table 2 Uni- and multivariate logistic regression of factors potentially influencing the risk for non-reversal of defunctioning stoma in rectal cancer surgery in northern Sweden 2007–2014. Asterisk indicates $P < 0.05$

Entire population <i>n</i> = 273	nr		No reversal	Odds ratio	Uni-variate 95% CI	<i>P</i> value	Odds ratio	Multivariate 95% CI	<i>P</i> value
Distance nearest hospital	60	1st quartile	20.0%	1.19	0.52–2.74	0.678			
	74	2nd quartile	23.0	1.00	Ref	Ref			
	69	3rd quartile	8.7	3.13	1.16–8.49	0.025 *			
	70	4th quartile	15.7	1.60	0.69–3.71	0.274			
Distance nearest 90th %	245	< 90th %	17.1%	1.00	Ref	Ref			
	28	> 90th %	14.3	1.24	0.41–3.76	0.702			
Distance operating hospital	66	1st quartile	27.3%	0.30	0.12–0.76	0.012 *	0.64	0.18–2.32	0.500
	70	2nd quartile	10.0	1.00	Ref	Ref	1.00	Ref	Ref
	68	3rd quartile	11.8	0.83	0.28–2.44	0.739	1.20	0.34–4.23	0.777
	69	4th quartile	18.8	0.48	0.18–1.28	0.143	0.82	0.24–2.87	0.767
Distance operating 90th %	204	< 90th %	17.1%	1.00	Ref	Ref			
	69	> 90th %	14.3	0.83	0.41–1.69	0.610			
Distance largest hospital	67	1st quartile	23.9%	0.80	0.35–1.79	0.58			
	67	2nd quartile	10.5	2.14	0.81–5.70	0.13			
	69	3rd quartile	13.0	1.67	0.67–4.15	0.27			
	70	4th quartile	20.0	1.00	Ref	Ref			
Distance largest 90th %	245	< 90th %	18.0%	2.84	0.65–12.44	0.165			
	28	> 90th %	7.1	0.52	Ref	Ref			
County	70	Jämtland	18.6%	1.17	0.55–2.48	0.684	1.30	0.47–3.59	0.617
	114	Västerbotten	21.1	1.00	Ref	Ref	1.00	Ref	Ref
	89	Norrbottnen	10.1	2.37	1.04–5.40	0.040 *	1.84	0.63–5.37	0.266
N stage	160	N0	13.1%	1.00	Ref	Ref	1.00	Ref	Ref
	66	N1	24.2	0.47	0.23–0.98	0.043 *	0.25	0.08–0.72	0.011 *
	46	N2	19.6	0.62	0.26–1.47	0.271	1.07	0.30–3.85	0.922
	1	Nx	100	1.00	omitted	omitted	1.00	omitted	omitted
M stage	249	M0	14.5%	1.00	Ref	Ref	1.00	Ref	Ref
	22	M1	45.5	0.20	0.08–0.50	0.001 *	0.14	0.03–0.57	0.006 *
	2	Mx	0	1.00	omitted	omitted	1.00	omitted	omitted

weakness of the study is that those patients operated towards the end of 2014 had follow-up times of around 32 months only, and later reversals could have been missed.

The reversal rate in this study was 83%. Compared to other studies, the reversal rate in the present study was normal to high [9, 26, 27]. Gustafsson et al. used a purely registry-based method and showed that the overall reversal rate in Sweden 2007–2013 was 82.9% which is very similar to the reversal rate in the present study. This is interesting because these two studies used different methods. This study was based on careful scrutiny of medical records. Twelve defunctioning stomas were removed from the denominator, and thanks to the longer follow-up time, 17 reversed stomas were added to the numerator, thereby increasing the reversal rate by nearly 10 percentages compared to what we would have found using their method. This suggests that the northern part of Sweden

actually has a lower reversal rate compared to the rest of the country. We consider the use of medical records as a source of information on defunctioning stomas and their reversal instead of using registry data only, to be a strength of this study.

In the linear regression model, mean distance to the nearest hospital for patients with a T1-tumor was 22 km compared to 51 km for those with a T4 tumor. This result is not significant ($p = 0.06$) but is compatible with the findings published by Massarweh et al. in 2014, that longer distance to the nearest hospital increases the likelihood of patients presenting with metastatic disease at diagnosis [14]. We also found that if stoma reversal was delayed, the mean distance to operating hospital was 102 km compared to 66 km in cases with no delay. This result is not significant ($p = 0.07$) but constitutes an interesting finding given our hypothesis. The analysis of

delayed stoma reversal contained only 227 cases which may be too low to have sufficient power.

In our multivariate logistic regression analysis, only metastatic disease and N1-stage were significant risk factors for non-reversal. Pan et al. also showed disseminated disease as a risk factor based on a similarly sized population [26]. In that study, Charlson Comorbidity Index score also fell out significant, a variable not included in our study. The lack of this variable is thus a weakness.

In the univariate model for non-reversal, some of the distance quartiles fell out significant in a manner indicating the opposite relationship to our hypothesis. That people living closer to the operating hospital have a higher likelihood of non-reversal (OR 0.30; 95% CI 0.12–0.76). These findings could not be supported in the multivariate model. Nevertheless, these results are important to interpret. As mentioned previously, the time to reversal reported in this study is remarkably longer compared to similar studies, likely due to a low priority of the procedure. That patients living closer to operating hospital (1st quartile) have a higher likelihood of non-reversal compared to patients living further away can therefore be interpreted as that the reversal procedure gains an even lower priority in the larger hospitals, which mainly perform the index surgery.

Since the reversal procedure itself is usually not considered to be complicated by surgeons, shortcomings in the health care organization fall under suspicion of being the reason for the delay. In all three regions, a lack of nurses is a major concern, which of course could affect the possibility of performing surgery. However, this lack of nurses is of similar magnitude in the entire Northern region and cannot be accounted for the difference. Instead, given these results, the centralization of surgical procedures to the larger hospital could very well be a contributing factor for these inequalities. Today, the larger hospitals in the counties included perform surgical procedures which previously were handled by the smaller hospital. As a consequence, the stoma reversal procedure has to compete against more complex and urgent surgery in the larger hospitals, further accentuating the low priority. Meanwhile, the defunctioning stoma remains with its associated problems.

The results of this investigation did not support our hypothesis that longer distance to hospital has a negative impact on the reversal rate of defunctioning stoma, increasing delay until reversal or the occurrence of permanent stoma. In fact, the opposite relationship was found in the univariate logistic regression analysis for non-reversal. We also found a clear trend in the linear regression analysis that patients with a longer distance to hospital are more likely to have their reversal delayed. Given the demography of this region, the first and second quartile distances correspond to urban districts. The overall interpretation of these results could be that patients whose follow-up is in the regime of a more distant local hospital get

their stomas reversed but must wait, given the low medical priority, while the defunctioning stomas in bigger cities with larger hospitals are forgotten and remain as a permanent issue to the individual patient.

Conclusions

Longer distance to hospital is not a risk factor for non-reversal of a defunctioning stoma; rather, patients living closer to the operating hospital have a significantly higher likelihood of non-reversal than those living further away. Only 23% of the patients had their stoma reversed within 6 months. Median time to reversal was 287 days (range 82–1557 days), suggesting that future studies need to have a long follow-up time if accurate stoma reversal rates are to be determined.

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Compliance with ethical standards

Ethics approval of this study was obtained from the Regional Ethics Committee in Umeå (Dnr 2016/155–31). For this type of study, formal consent from each patient is not required. The authors declare that they have no conflicts of interest in this study.

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