Patient education after stoma creation may reduce health-care costs

Anne Kjærgaard Danielsen & Jacob Rosenberg

ABSTRACT

INTRODUCTION: Researchers are urged to include health-economic assessments when exploring the benefits and drawbacks of a new treatment. The aim of the study was to assess the costs associated with the establishment of a new patient education programme for patients with a stoma.

MATERIAL AND METHODS: Following a previous case-control study that explored the effect of patient education for stoma patients, we set out to examine the costs related to such a patient education programme. The primary outcome was disease-specific health-related quality of life measured with the Ostomy Adjustment Scale six months after surgery. The secondary outcome was generic health-related quality of life measured with Short Form (SF)-36. In this secondary analysis, we calculated direct health-care costs for the first six months post-operatively from the perspective of the health-care system, including costs related to the hospital as well as primary health care.

RESULTS: The overall cost related to establishing a patient education programme showed no significant increase in the overall average costs. However, we found a significant reduction in costs related to unplanned readmissions ($p = 0.01$) as well as a reduction in visits to the general practitioner ($p = 0.05$).

CONCLUSION: Establishing a patient education programme – which increased quality of life – will probably not increase the overall costs associated with the patient course.

FUNDING: The study received financial support from Søster Inge Marie Dahlgaards Fond, Diakonissestiftelsen, Denmark, and from Aase and Ejnar Danielsens Foundation, Denmark.

TRIAL REGISTRATION: NCT01154725.

Demands on health-care urge researchers to include economic assessment tools to support the implementation of new and beneficial interventions [1]. A cost calculation may thus help to underpin professional decision-making when new treatments and methods are introduced in the health care [2, 3]. Stomas are constructed for different reasons, and it is well known that stoma creation affects patients, although the impact on the individual varies [4, 5]. We therefore set up a study aiming at increasing patients' adaptation to living with a stoma, the results of which were reported in detail elsewhere [6]. We found that patient education and telephone follow-up positively affected treatment outcome of health-related quality of life (HRQOL). In our study, both groups received standard treatment and care related to stoma creation, and only patients in the intervention group received patient education and telephone follow-up. The results of the study were a significant increase in HRQOL in the intervention group [6]. After concluding the study, we performed the analysis reported herein of the costs of the new interventions six months after stoma creation.

MATERIAL AND METHODS

We performed a cost analysis on the basis of a case-control study including 50 patients admitted to the Department of Surgery for Stoma Creation. We first studied the control group who received routine care. Sub-sequently, the intervention was implemented and a new group of patients was included. Patients were included following fixed inclusion and exclusion criteria in the period from August 2010 to June 2011 with a follow-up period of six months after surgery.

Outcomes

The main objective of the cost analysis was to explore whether the interventions would increase or reduce the costs related to the patient course. The course included both the initial hospital stay and the rehabilitation period following discharge.

Sample size

The sample size was calculated before initiating the study, and it was related to its primary outcome which was HRQOL measured with the Ostomy Adjustment Scale [6].

Cost assessment

The study measured all direct health-care costs for the first six months post-operatively from the perspective of the health-care system. The costs included costs related to the hospital as well as primary care.

We applied a cost measurement based on patients' use of health care, including length of hospital stay, visits at the out-patient stoma clinic, visits with the general practitioner (GP) and with a primary care nurse [7]. We applied a judgment based on predefined and fixed measures of whether the variables were due to stoma-

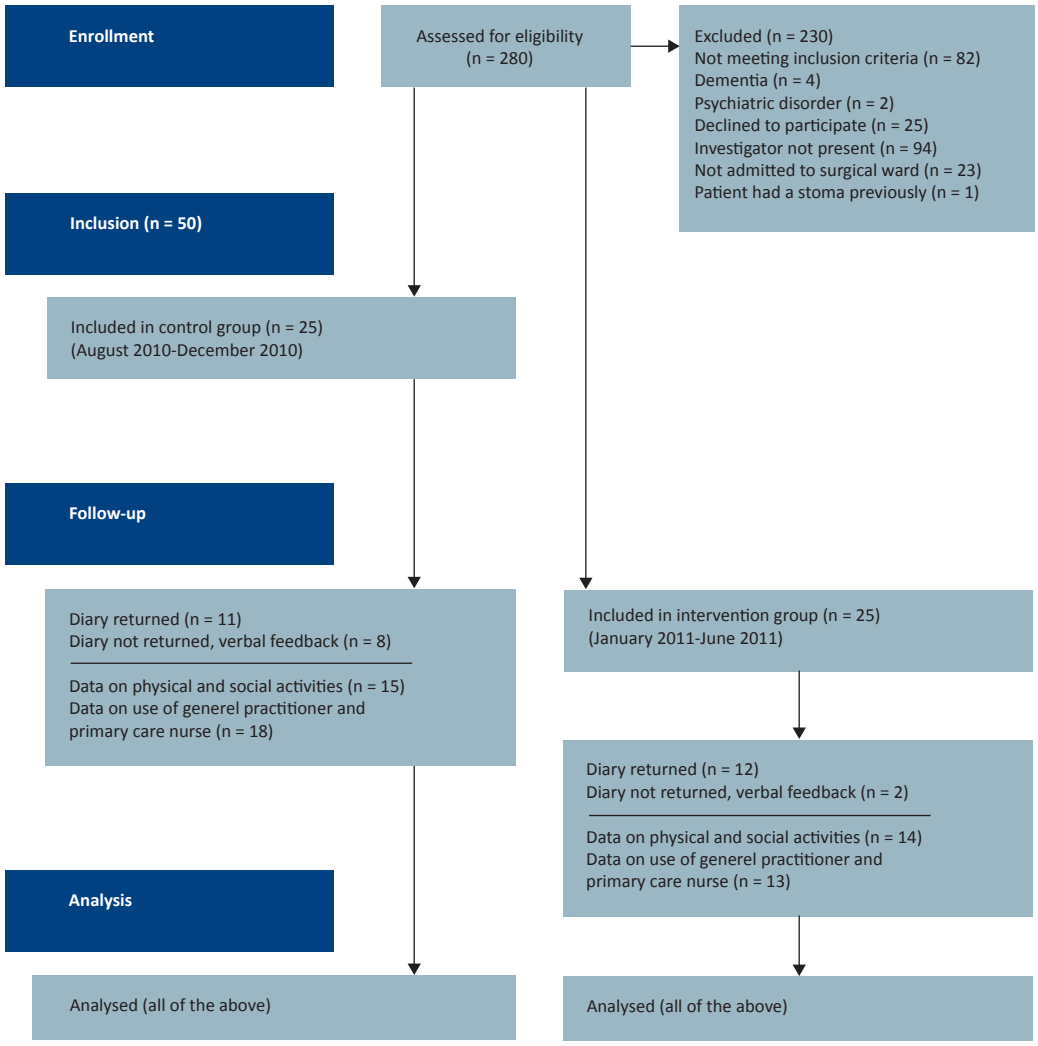
ORIGINAL ARTICLE

Centre for Perioperative Optimization, Department of Surgery, Herlev Hospital

Dan Med J 2014;61(4):A4659

FIGURE 1

Flow chart illustrating the sequential inclusion of 25 participants in the control group followed by 25 partici-pants in the intervention group.



related symptoms and issues or not [8]. We registered patients being readmitted to the surgical department for reasons related to stoma handling, including bandaging, skin care and nutritional needs. We excluded patients re-admitted for a pathologically high stoma output. The data on length of hospital stay and re-admittance to hospital were based on data from the hospital registry.

Direct costs were registered, analyzed and presented [9], e.g. teachers' hours spent preparing for the teaching session and delivering the teaching session. The indirect costs when developing the programme were registered related to the time that the enterostoma therapist (ET) spent in the developing phase. However, resources spent by the first author were not registered as assessment of the operational costs should not include resources used in the developmental phase.

Moreover, we made an overall assessment of the budget impact per patient participating in the educational programme, and calculated the mean difference in total costs based on the actual observations.

Finally, we registered the number of days that elapsed until the patients resumed normal activities as self-inflicted isolation could be a barrier to adaptation to living with a stoma [10].

The analyses were thus a comparison of the costs (in absolute values) used in the control and the intervention group. Costs were registered either as time spent (hours, minutes) or as number of visits, and the costs were then calculated by multiplying the unit cost in Danish Kroner by the number of units used. Data from primary care were self-reported by patients who filled in a patient diary with text box options [11]. Data from the out-patient clinic and information about length of hospital stay were attained through the hospital registry.

TABLE 1

Costs per patient in the control group and intervention group, respectively. Costs are reported in DKK (2012-values) and the statistical analyses are based on the Mann-Whitney test.

	Control group (n = 18)		Intervention group (n = 13)		
	mean (SD)	median (range)	mean (SD)	median (range)	p-value
Developmental costs	0	0	154.5 (0)	154.5 (0-154)	–
Patient education programme	0	0	422 (0)	422 (0-422)	–
Subtotal intervention cost/patient	0	0	576.5 (0)	567.5 (0-567)	–
Outpatient clinic					
Preoperative	74 (92)	0 (0-184)	66 (90)	0 (0-184)	1
Post-operative	714 (464)	552 (0-2,259)	626 (404)	736 (0-1288)	0.76
Telephone support	59 (102)	0 (0-368)	88 (168)	0 (0-552)	0.99
Hospital stay	95,120 (76)	72,500 (29,000-398,750)	91,640 (88,569)	58,000 (43,500-456,750)	0.56
Unplanned readmissions	4,640 (9,563)	0 (0-36,250)	0	0	0.01
General practitioner	155 (333)	0 (0-1141)	0	0	0.05
Primary care nurse	1,708 (4,961)	0 (0-20,572)	960 (3403)	0 (0-12,285)	0.18
Total costs for 1 patient	101,948 (77,672)	88,685 (29,552-40,655)	93,495 (89,137)	58,576 (44,628-458,430)	0.43

SD = standard deviation.

Data analysis

Data analysis was based on descriptive statistics and nonparametric tests using the Statistical Package for the Social Sciences (IBM SPSS Statistics 19). Descriptive data were reported as mean with standard deviation or median with range. Comparisons between the groups were made using the Mann Whitney test or Fisher's exact test, where applicable. Statistical significance was set at $p \leq 0.05$. Furthermore, we performed a missing data analysis using binary logistic regression.

Ethics

Data processing approval of the study was obtained from the Danish Data Protection Agency (J. no. 2010-41-4706). The study was performed in compliance with the ethical principles of the World Medical Association's Declaration of Helsinki. However, the Danish Regional Scientific Ethics Committee evaluated that the study was exempt from approval (H-2-2010-041). Furthermore, the study was notified on clinicaltrials.gov (NCT01154725).

RESULTS

Seventy-five of 280 eligible patients were invited to participate. In all, 25 of these declined and we thus included 25 patients in each group [6] (**Figure 1**). Baseline characteristics and missing data analysis showed no significant differences between the groups [6]. However, the baseline scores on the Ostomy Adjustment Scale were significantly lower in the intervention than in the control group ($p = 0.045$).

Overall costs associated with the introduction of the patient education programme

The overall costs were based on a per-patient average and showed no significant difference between the groups associated with the introduction of patient education (**Table 1**). The total costs showed a difference between the two groups equivalent to a mean cost reduction of 8,453 DKK/patient in favour of the intervention group. However, this difference was not significant.

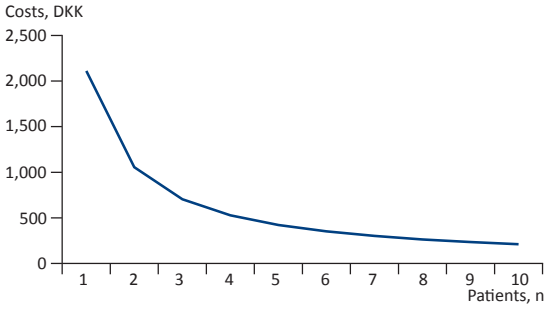
Length of hospital stay and readmissions after discharge from hospital

Length of hospital stay was calculated from the day of surgery until discharge from hospital (control group: mean 12.6 days (standard deviation (SD) 12.2), intervention group: mean 13.1 days (SD 10.5)). No difference between the groups was seen. In the control group, seven patients were readmitted within six months after stoma creation (median two days, range 1-4 days), and no patients in the intervention group were readmitted ($p = 0.01$).

Education session. Photo: Thomas Hommelgaard.

FIGURE 2

The decrease in average costs per patient when increasing the number of participants one by one. Teaching by enterostoma therapists = 184 DKK/h, teaching by physiotherapists = 181 DKK/h and nurse/sexologist = 184 DKK/h.



Development costs

The first author developed the educational programme in cooperation with the ET on a 7-h workshop, generating a total cost of 3,864 DKK. Although development costs were resources only spent once, resource use for the ETs seemed relevant to report in order to clarify the opportunity costs of the activity.

Teachers' hours spent (only for the intervention group)

All patients in the intervention group had three 3-h teaching sessions, which resulted in a total of 9 h of teaching for all the involved ET teaching. Furthermore, a physiotherapist taught for 1.5 h/group and a sexologist for 1 h/group. The costs related to the sessions in the educational programme were in total 2,111 DKK for the three educational sessions. During the study period, five groups were set up and the costs related to the establishment of a group were identical regardless of the number of participants. Thus, we calculated the total costs divided by number of participants, showing how an increasing number leads to a decrease in the average costs (**Figure 2**) [12].

Costs related to the patients' course outside of the hospital

In the control group, 11 patients returned the patient diary and eight provided face-to-face feedback. In the intervention group, 12 patients returned the diary and two provided face-to-face feedback. We found that only patients in the control group reported visits with the general practitioner which resulted in a significant difference between the groups (p = 0.05). Patients in both groups needed occasional help from the primary nurse in the community; no significant differences between the groups were observed (p = 0.18). In addition, the data revealed that patients in both groups had assistance from family and friends related to the stoma creation with no significant differences between the groups (p = 0.16).

Support from the enterostoma therapist at the out-patient clinic

Patients in both groups needed the support from the ET, and the costs were calculated in DKK based on salary per hour of hospital nurses, and on data from the hospital registry [13]. There were no significant differences between the groups concerning preoperative visits (p = 1), post-operative visits (p = 0.76) or telephone support (p = 0.99).

Time until resumption of physical and social activities

Patients in both groups were urged to resume normal activities as soon as possible. Patients in both groups resumed physical and social activities within the first 4-5 weeks with no differences between the groups (physical activity: p = 0.8, social activity: p = 0.6) Data were based on the patients' own reports in diaries.

DISCUSSION

Establishing the patient education programme yielded a significantly increased quality of life for patients, and the cost analysis has demonstrated that there was no significant increase in total costs. With regard to differences in mean costs, we found a single although statistically insignificant difference. However, we did find a significant reduction in the costs of unplanned readmissions as well as a reduction in assistance needed from GPs in the intervention group. One of the aims of our study was to identify, measure, value and compare relevant costs and consequences [14]. We designed a case-control study that allowed us to evaluate the cost of a clinical intervention as we enrolled patients with typical caseloads [3]. However, when including participants in the study, we selected patients who would be able to attend the activities related to educational sessions. This might, in turn, have excluded some patients who were not physically or mentally prepared for this.

The measured costs in this project were related to the health-care sector and involved visits at the out-patient stoma clinic, visits with GPs and a primary care nurse [8]. In a previous study, readmission rates after creation of a loop-ileostomy were found to reach 16.9%, with a mean length of stay of 8.2 days, and with dehydration as the major cause [15]. Unplanned readmissions related to stoma creation were prevented, and we propose that patient education may prevent readmission related to less severe symptoms, which is in line with a recent single-group study [16].

The costs of the teaching sessions were registered as a total and not stated per participating patient. How-

ever, when analyzing the marginal costs, it became apparent that by including more participants, the costs of the educational activities per patient could be reduced owing to economics of scale. The result of raising the number of participants to for instance eight instead of five would reduce costs, presumably without hampering achievement of the educational aim. However, there are no empirical recommendations regarding group size, and it is usually set at a manageable number that both complies with the need for interaction between participants and the need for individualization [17]. Nevertheless, the maximum number of participants should be considered when expanding any educational programmes, as the first new participant in a new group would not reduce, but increase costs.

A cost analysis is a tool for making these decisions in the clinical setting [18], and it may support a professional process of prioritizing when new treatments and methods are introduced [19]. In this study, the findings showed an increase in HRQOL; and as the economic assessment did not reveal differences in the overall cost related to the intervention, this would be a supportive argument in implementing the intervention. However, the drop-out rate, especially the non-randomized design, and the proportion of patients who were not included in the study are limitations which might have biased the results showing that the cost of the intervention was 576 DKK (Table 1). Moreover, questions regarding opportunity costs may be difficult to assess, because in our study the ETs could have carried out other relevant clinical tasks, which should also be acknowledged in a cost analysis.

Furthermore, the relatively high drop-out rate may have produced overoptimistic results regarding the analysis of the mean costs, as the actual calculations were, in fact, carried out on a small number of participants. In order to increase the level of evidence, we would suggest that future studies were designed as large scale studies as it is difficult to perform a randomized controlled trial with this type of intervention.

The use of patient diaries is a limitation of this study as patients may have underreported or over-reported activities. This may be particularly relevant for the patients who provided oral feedback, as they might have forgotten some of their actual activities. The validity of the patient-reported data may therefore be low. On the other hand, data about readmissions and length of hospital stay were obtained from the hospital registry, and therefore we assume that these are valid.

In conclusion, we have found that the establishment of a patient education programme after stoma creation increased HRQOL significantly and that it would probably not increase the average total cost. Furthermore, we found that costs related to visits with the GP as well as unplanned readmissions after stoma creation were reduced significantly.

CORRESPONDENCE: *Anne Kjærgaard Danielsen*, Gastroenheden, Herlev Hospital, 2730 Herlev, Denmark. E-mail: anne.k.danielsen@gmail.com

ACCEPTED: 23 April 2013

ACKNOWLEDGEMENTS: We would like to extend our gratitude to *Tine Marie Kjærgaard Danielsen* for statistical support.

CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at www.danmedj.dk.

LITERATURE

1. Coast J. Is economic evaluation in touch with society's health values? BMJ 2004;329:1233-6.
2. Canales MG, Macario A, Krummel T. The surgical suite meets the new health economy. J Am Coll Surg 2001;192:768-76.
3. Petrou S, Gray A. Economic evaluation alongside randomised controlled trials: design, conduct, analysis, and reporting. BMJ 2011;342:d1548.
4. Nugent KP, Daniels P, Stewart B et al. Quality of life in stoma patients. Dis Colon Rectum 1999;42:1569-74.
5. Brown H, Randle J. Living with a stoma: a review of the literature. J Clin Nurs 2005;14:74-81.
6. Danielsen AK, Rosenberg J. Health related quality of life may increase when patients with a stoma attend patient education – a case-control study. PLoS One 2014 (in press).
7. Dowson HM, Gage H, Jackson D et al. Laparoscopic and open colorectal surgery: a prospective cost analysis. Colorectal Dis 2012;14:1424-30.
8. Thorsteingsdottir T, Stranne J, Carlsson S et al. LAPRO: a prospective multicenter comparative study of robot-assisted laparoscopic radical prostatectomy for prostate cancer. Scand J Urol Nephrol 2011;45:102-12.
9. Welch JL, Fisher ML, Dayhoff NE. A cost-effectiveness worksheet for patient-education programs. Clin Nurse Spec 2002;16:187-92.
10. Danielsen AK, Soerensen EE, Burcharth K et al. Impact of a temporary stoma on patients´everyday lives: feelings of uncertainty while waiting for closure of the stoma. J Clin Nurs 2013;22:1343-52.
11. Goossens ME, Rutten-van Mölken MP, Vlaeyen JW et al. The cost diary: a method to measure direct and indirect costs in cost-effectiveness research. J Clin Epidemiol 2000;53:688-95.
12. Alban A, Danneskjold-Samsøe B, Christensen JK et al. Sundhedsøkonomi. Principper og perspektiver [Health economics. Principles and perspectives]. Copenhagen, Denmark: DSI Institut for Sundhedsvæsen, 1999:3-246.
13. Danish Nurses Organisation, 2012. www.dsr.dk/Artikler/Sider/Forhandling/L%C3%B8nstatistik-for-sygeplejersker-ansat-i-kommuner-og-regioner.aspx (28 Nov 2012).
14. Drummond M, Sculpher MJ, Torrance GW et al. Methods for the economic evaluation of health care programmes. 3rd ed. Oxford: Oxford University Press, 2005.
15. Messaris E, Sehgal R, Deiling S et al. Dehydration is the most common indication for readmission after diverting ileostomy creation. Dis Colon Rectum 2012;55:175-80.
16. Nagle D, Pare T, Keenan E et al. Ileostomy pathway virtually eliminates readmissions for dehydration in new ostomates. Dis Colon Rectum 2012;55:1266-72.
17. Wofford JL, Wells MD, Singh S. Best strategies for patient education about anticoagulation with warfarin: a systematic review. BMC Health Serv Res 2008;8:1-8.
18. Finlayson SR, Birkmeyer JD. Cost-effectiveness analysis in surgery. Surgery 1998;123:151-6.
19. van den Hout WB, van den Brink M, Stiggelbout AM et al. Cost-effectiveness analysis of colorectal cancer treatments. Eur J Cancer 2002;38:953-63.