Palliative Medicine

The Liverpool Care Pathway for cancer patients dying in hospital medical wards: A before−after cluster phase II trial of outcomes reported by family members

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Massimo Costantini[1], Fabio Pellegrini[2,3], Silvia Di Leo[1],
Monica Beccaro[1], Carla Rossi[4], Guia Flego[5], Vittoria Romoli[1],
Michela Giannotti[5], Paola Morone[5], Giovanni P Ivaldi[4],
Laura Cavallo[5], Flavio Fusco[6] and Irene J Higginson[7]

Abstract

Background: Hospital is the most common place of cancer death but concerns regarding the quality of end-of-life care remain.
Aim: Preliminary assessment of the effectiveness of the Liverpool Care Pathway on the quality of end-of-life care provided to adult cancer patients during their last week of life in hospital.
Design: Uncontrolled before–after intervention cluster trial.
Settings/participants: The trial was performed within four hospital wards participating in the pilot implementation of the Italian version of the Liverpool Care Pathway programme. All cancer patients who died in the hospital wards 2–4 months before and after the implementation of the Italian version of Liverpool Care Pathway were identified. A total of 2 months after the patient's death, bereaved family members were interviewed using the Toolkit After-Death Family Interview (seven 0–100 scales assessing the quality of end-of-life care) and the Italian version of the Views of Informal Carers - Evaluation of Services (VOICES) (three items assessing pain, breathlessness and nausea-vomiting).
Results: An interview was obtained for 79 family members, 46 (73.0%) before and 33 (68.8%) after implementation of the Italian version of Liverpool Care Pathway. Following Italian version of Liverpool Care Pathway implementation, there was a significant improvement in the mean scores of four Toolkit scales: respect, kindness and dignity (+16.8; 95% confidence interval = 3.6–30.0; p = 0.015); family emotional support (+20.9; 95% confidence interval = 9.6–32.3; p < 0.001); family self-efficacy (+14.3; 95% confidence interval = 0.3–28.2; p = 0.049) and coordination of care (+14.3; 95% confidence interval = 4.2–24.3; p = 0.007). No significant improvement in symptom' control was observed.
Conclusions: These results provide the first robust data collected from family members of a preliminary clinically significant improvement, in some aspects, of quality of care after the implementation of the Italian version of Liverpool Care Pathway programme. The poor effect for symptom control suggests areas for further innovation and development.

Keywords

Cancer, palliative care, end-of-life care, Liverpool Care Pathway, hospital, quality of health care

Introduction

Death in hospital remains very common for cancer patients in developed countries.[1,2] Although hospital surveys show that death was highly expected for over two-thirds of the patients,[3,4] patients dying in hospital have a high probability of unrelieved and poorly treated physical suffering, and emotional, spiritual and social distress.[3–6]

Specialist palliative care services significantly improve patient outcomes in physical and psychological domains, reduce hospital admissions and, in some studies, are associated with a higher degree of satisfaction for patients and family members.[7,8] Quality improvement programmes in

[1]Regional Palliative Care Network, IRCCS AOU San Martino-IST, Genoa, Italy
[2]Mario Negri Sud Institute, Mario Negri Sud Consortium, Chieti, Italy;
[3]Unit of Biostatistics, Scientific Institute Casa Sollievo della Sofferenza, San Giovanni Rotondo, Italy
[4]Unit of Respiratory Disease, Villa Scassi Hospital, ASL 3 Genovese, Genoa, Italy
[5]Unit of Internal Medicine, Villa Scassi Hospital, ASL 3 Genovese, Genoa, Italy
[6]Home Care Palliative Care Unit, ASL 3 Genovese, Genoa, Italy
[7]Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, King's College London, London, UK

Corresponding author:
Massimo Costantini, Regional Palliative Care Network, IRCCS AOU San Martino-IST, Largo R. Benzi, 10, 16132, Genoa, Italy.
Email: costantini.massimo@asmn.re.it

the United States and United Kingdom suggest that aspects of the 'excellent practice' of palliative care can be transferred to other settings.[9,10] The Liverpool Care Pathway (LCP) for the dying patient is one pathway that seeks to achieve this.[10] It offers a structured programme aimed at providing improvements in the quality of care for all relevant dimensions at the end of life: symptom control, comfort and psychological-insight measures, religious-spiritual support and communication with the patient, the family and care team.

Although the LCP programme is becoming popular, and was advocated for national roll-out in the United Kingdom, evidence supporting its effectiveness is scarce.[11] Qualitative[12–14] and quasi experimental[15,16] studies suggest that the LCP can be effective in improving the quality of documentation, reducing the use of potentially life-shortening medication and in some small studies, improving communication. However, information on the effect on patient and family outcomes, in particular symptom control, is lacking.

In 2006, the Italian Minister of Health funded a 3-year research programme with the general aim to determine whether the implementation of the LCP in a hospital setting is effective in improving the quality of end-of-life care provided to cancer patients. The original LCP documentation was translated and adapted to the Italian context, and the programme subsequently piloted in four medical wards of the Villa Scassi Hospital of Genoa. The implementation process was evaluated using a combined qualitative and quantitative approach.[14,17,18] The methodological issues in designing the before–after study and interpreting the results in terms of compliance and adherence to the planned procedures were previously discussed and critically evaluated.[17]

In this article, we report the results of the before–after study to assess the preliminary effectiveness of the LCP on the quality of end-of-life care provided to cancer patients during their last week of life in hospital, based on outcomes as assessed by family members and the process of communication between hospital staff and general practitioners (GPs).

Methods

Study design

This is an uncontrolled before–after intervention cluster trial performed within four hospital wards participating in the pilot implementation of the Italian version of the LCP (LCP-I) programme.

Setting

The LCP-I programme was piloted in the three general medicine wards and in the respiratory disease ward of Villa Scassi Hospital in Genoa (Italy). At the time of the study,

the three general medicine wards had 72 beds (with 11 physicians and 39 nurses), and the respiratory disease ward had 24 beds (with 8 physicians and 17 nurses). In 2006–2007, approximately 350 deaths occurred in the general medicine ward (with around 150 from cancer), and 109 deaths occurred in the respiratory disease ward (with around half of these from cancer).

The implementation of the LCP-I programme

The original English version 11 of the LCP for hospital and the Goal Data Dictionary were translated into Italian, in compliance with the original format. The procedures of implementation originally described in the 10-step Continuous Quality Improvement Programme were slightly adapted to the Italian context. The LCP-I was endorsed by the LCP Central Team of the Marie Curie Palliative Care Institute Liverpool (MCPCIL), and subsequently piloted in the four wards.[19] A detailed description of the LCP-I programme has been previously reported.[14]

The LCP-I programme includes a preliminary phase of development of the implementation project (steps 1–3), followed by the experimental phase of LCP-I implementation into the four wards (steps 4–8). The experimental phase was driven by a specialized palliative care team (PCT) comprising two physicians, three nurses and two psychologists. This phase lasted 6 months and was performed between March and September 2007 in the three general medicine wards and between September 2008 and March 2009 in the respiratory disease ward. It started with an intensive training phase (step 4) targeted at all nurses and physicians of the hospital wards. Afterwards, the ward staff, closely supported by the PCT, started using the LCP-I clinical documentation for all dying patients (steps 5–8). The PCT supported and supervised the implementation process through repeated coaching, telephone and direct guidance and discussion of clinical cases and clinical audits. Finally, the LCP-I file was proposed as a routine procedure in the ward and was included into the continuous hospital quality improvement programme (step 9). The project outcomes were used to stimulate discussions at a regional and national level regarding issues linked to the quality of end-of-life care (step 10).

Inclusion and exclusion criteria

All patients aged 18 years or above who died from cancer according to standard criteria (ICD-IX 140-239) in the general medicine wards in the 4 months before and after the experimental LCP-I implementation (steps 4–8) were consecutively identified from the hospital record system. Due to budget limitation, the assessment in the respiratory disease ward was limited to the 2 months before and after the LCP-I implementation. Patients who were a relative of a

professional working in the ward were considered ineligible and excluded from the study.

Procedures of assessment

The quality of care received by the adult dying cancer patients and their families was evaluated using the post-bereavement approach. For each eligible deceased patient, the family member closest to the patient during his or her last week of life in the ward, and his or her GP were identified from the medical records. A telephone interview with the GP was conducted on two aspects: confirmation or integration of information regarding the patient's family member and communication between ward staff and the GPs.

A total of 2 months after the patient's death, a letter was sent to all identified family members informing them of the study aims and requesting their consent to be interviewed. If the family member agreed to participate in the study, the interviewer met him or her, usually at home. A telephone interview was proposed only when the face-to-face interview was not feasible.

The assessment

Quality of end-of-life care was measured with the 'Toolkit After-Death Family Interview' (Toolkit) and with some items from the Italian version of the post-bereavement survey tool 'VOICES'.[20,21] Both instruments were assembled in the semi-structured interview proposed to the family member. The interview was focused on the last week of life in the ward.

The Toolkit is a structured interview developed and validated by Teno and colleagues[22,23] in 2001 to measure quality of care at the end of life from the perspective of bereaved family members. The interview, based on a patient-focused, family-centred conceptual model of care,[22] explores whether end-of-life care meets the expectations and needs of the dying person and their family members. The Toolkit was translated into Italian following European Organisation for Research and Treatment of Cancer (EORTC) guidelines. It contains 33 open-ended questions (plus 1 filter question) that can be grouped into 7 scales (Table 1).

We calculated the scale scores as reported by Teno and colleagues.[23] Each question of scales 1–5 has one correct response and one or more negative responses. The proportion of correct responses of a scale is the score of that scale. The scale 6 exploring the self-efficacy of the family has three questions with three possible answers (very confident = 3, fairly confident = 2, and not confident = 1). The scale 7 (overall rating) includes six questions exploring the main domains of care at the end of life: communication with patient and family, respected wishes of the patient, symptom control, dying with dignity, emotional support to the family and overall care received. The family member was asked to rate each question on a 0–10 scale where 0 means

the worst and 10 means the best care possible. For ease of interpretation, all scales were linearly transformed to a 0–100 scale where 100 is the best quality of care. The scores of the scales with ≤50% missing items were estimated using the available items.

A section of the interview covered information on the prevalence of three symptoms (pain, breathlessness and nausea-vomiting) and the treatment received during the last 3 days of life in the ward derived from the Italian version of the VOICES.[20,21] For each symptom, the interview explored whether the patient had been affected by the symptom and how much the family member thought the symptom distressed the patient (not at all, a little, much or very much). For the patients with the symptom, the interview explored whether a treatment had been administered and how much it had relived the symptom (not at all, a little, much or very much).

For each symptom, we estimated the proportion of patients with the symptom (yes vs no), who received a treatment (yes vs no) and with a positive outcome from the treatment (much–very much vs not at all–a little). An overall indicator of symptom control was estimated by aggregating the patients without the symptom with the patients with the symptom who received a treatment that relieved the symptom much or very much (group A). Conversely, the patients with the symptom who either did not receive any treatment or received a treatment that relived the symptom not at all or a little were aggregated together (group B). The overall indicator is proportion of patients with good control of the symptom (group A divided by group A + group B).

The communication between ward professionals and GPs was evaluated by means of two questions administered in a telephone interview after the patient's death: whether the GP was informed by the ward about the dying phase and about the patient's death.

Statistical analyses

Characteristics of the evaluated samples are reported as mean and standard deviation (SD) or frequencies and percentages. Although this exploratory study was not formally designed to test a pre-defined hypothesis, we reported the *p*-values of the tests performed for comparing the two samples. Comparisons between the two samples (before and after the LCP-I implementation) were assessed with *t*-test and Pearson chi-squared test for continuous and categorical variables, respectively. Continuous (the seven Toolkit scales) and categorical outcomes (the VOICES scales) were analysed with a generalized hierarchical linear model to account for clustering within the four wards using an unstructured correlation matrix.[24] The clusters were the aggregation of patients from the same ward. A high degree of internal intra-class correlation (ICC) for all the Toolkit scales was observed.[17] Results were reported as

Table 1. The Italian version of the 'Toolkit After-Death Family Interview'.

Domains	Scales	Objectives	Items
Shared decision-making	Informing and making decisions	Patients and families are appropriately informed about illness, disease trajectory and therapies. Medical decisions reflect the patients' desired involvement and informed preferences.	8
	Advance care planning	Health-care providers communicate and negotiate with the patient regarding goals of care, so that their preferences are honoured.	3
Focus on individual	Respect, dignity and kindness	The dying person is treated with respect, dignity and kindness. This includes helping the patient achieve their desired level of control over their functioning and daily activities.	6
Family needs	Emotional support, including both prior and after the patient's death	The family receives the desired support at time prior to and after the patient's death, including appropriate referral for bereavement support.	3
	Self-efficacy of the family	Family members have the confidence in their ability to help the dying person in management of their medical care	3
	Spiritual support	Someone has appropriately talked with the family about their religious or spiritual belief	1
Coordination of care	Coordination of care	Consistent and coordinated care across settings and services are provided for patients and families	4
Overall	Overall quality of care	Summary assessment of the main dimensions of care	6

cluster-adjusted means, percentages and odds ratios (ORs) along with their 95% confidence intervals (CIs). The project protocol was approved by the Ethical Committee of the National Cancer Institute of Genoa and of the Villa Scassi Hospital (Prot. 17-7 2007).

Results

A total of 115 consecutive patients who died from cancer in the four wards of the Villa Scassi Hospital were identified: 65 before and 50 after LCP-I implementation. Four patients were excluded as relatives of hospital professionals, leaving a final sample of 111 eligible patients (63 before and 48 after).

Interviews were conducted with 79 family members, 46 (73.0%) before and 33 (68.8%) after LCP-I implementation. Of the 32 not-interviewed, 7 (6.3%) could not be located and 25 (22.5%) refused to be interviewed. The characteristics of the two study samples and the compliance at assessment have been previously described and analysed.[17] No major differences in the characteristics of the patients and the family members were observed between the two samples (Table 2). Conversely, the interval between the patient's death and the interview was significantly ($p = 0.013$) greater in the 'before sample'. The proportion of telephone interviews increased in the 'after sample' (36.4%) as compared to the 'before sample' (6.5%; $p = 0.001$).

Following LCP-I implementation, there was a significant improvement in the mean scores of four Toolkit scales: respect, kindness and dignity, family emotional support,

self-efficacy of the family and coordination of care. The effect sizes for these four variables ranged between 0.47 (self-efficacy of the family) and 0.77 (family emotional support) (Table 3).

The mean scores of the scale 'respect, dignity and kindness' increased significantly from 56.3 to 73.1 ($p = 0.015$). Similarly, the two scales and the item related to the family needs domain increased significantly: the 'family emotional support' scale increased from 30.9 to 51.9 ($p < 0.001$) and the 'self-efficacy of the family' scale increased from 42.7 to 57.0 ($p = 0.049$) (Table 3). A significant higher proportion of family members reported that some professional had '… appropriately talked with them about their religious or spiritual belief' after the LCP-I implementation (15%; 95% CI = 4.2–42.2) than before (0.1%; 95% CI = 0–2.4; $p = 0.002$). Also the mean scores of the scale 'coordination of care' increased significantly from 73.1 to 87.3 ($p = 0.007$).

The scale 'advance care planning' was estimated for only 17 patients (12 before and 5 after) because only 21.5% family members (26.1% before and 15.2% after; $p = 0.243$) answered YES to the filter question ('Did the patient have any specific wishes or plans about the types of medical treatment he/she would have wanted – or wouldn't have wanted – during the last days of life?').

After the LCP-I implementation, no differences in the overall control of pain and breathlessness, but a small improvement in nausea-vomiting, (OR = 2.3; 95% CI = 0.6–9.5; $p = 0.261$) was observed (Table 4).

There were few differences in the extent that GPs received a communication from the ward staff when the

Table 2. Characteristics of the assessed samples before and after LCP-I implementation.

	Before (n = 46)		After (n = 33)		p value
Age (Mean ± SD)	75.3 ± 9.1		73.0 ± 9.8		0.284
Gender					
Males	30	65.2	18	54.5	0.338
Females	16	34.8	15	45.5	
Primary tumour					
Digestive system	12	26.1	4	12.1	0.381
Respiratory system	21	45.7	16	48.5	
Genitourinary system	6	13.0	4	12.1	
Haematological	4	8.7	3	9.1	
Others	3	6.5	6	18.2	
Days in hospital (median range)	10 (2–44)		14 (1–110)		0.282
Days in ward (median range)	8.5 (1–43)		10 (1–70)		0.564
Family members					
Spouse	17	37.0	13	39.4	0.377
Child	25	54.3	14	42.4	
Other	4	8.7	6	18.2	
No family members	–	–	–	–	
Hospital ward					
General medicine I	8	17.4	8	24.2	0.548
General medicine II	15	32.6	10	30.3	
General medicine III	14	30.4	6	18.2	
Respiratory disease	9	19.6	9	27.3	
The interviews					
Interval death-interview (days)					
Mean ± SD	145.7 ± 22		130.0 ± 33		0.013
Interview modality					
Face to face	43	93.5	21	63.6	0.001
By telephone	3	6.5	12	36.4	

LCP-I: Italian version of the Liverpool Care Pathway; SD: standard deviation.
Values are numbers (column percentages) unless stated otherwise.

Table 3. Distribution and differences of the Toolkit scales scores before and after LCP implementation.

	Before (n = 46)		After (n = 33)		Difference		p value	Effect size
	n	Mean	n	Mean	Mean	(95% CI)		
Informing and making decisions	46	62.5	31	73.4	10.9	(−3.1–24.9)	0.130	0.35
Advance care planning[a]	12	51.4	5	82.4	31.0	(−2.4–64.4)	0.092	0.83
Respect, dignity and kindness	46	56.3	33	73.1	16.8	(3.6–30.0)	0.015	0.53
Family emotional support	44	30.9	32	51.9	20.9	(9.6–32.3)	<0.001	0.77
Coordination of care	46	73.1	33	87.3	14.3	(4.2–24.3)	0.007	0.57
Self-efficacy of the family	44	42.7	29	57.0	14.3	(0.3–28.2)	0.049	0.47
Overall quality of care	45	64.0	33	73.1	9.1	(−1.7–19.9)	0.103	0.35

LCP: Liverpool Care Pathway; CI: confidence interval.
[a]Scores estimated for 17 family members who answered YES to the filter question 'Did the patient have any specific wishes or plans about the types of medical treatment he/she would have wanted – or wouldn't have wanted – during the last days of life?'.

patient was dying (2.5% before vs 5.5% after; *p* = 0.389) and after the patient death (3.2% before vs 8.7% after; *p* = 0.239).

Discussion

The results from this before–after study found that LCP-I implementation in hospital is associated with a significant improvement in four out of seven patient-focused, family-centred outcomes. The family members reported that their emotional and spiritual needs were better attended, and they had better confidence in their self-efficacy. This supports our earlier small qualitative study.[14]

A substantial improvement was also observed in the dimension exploring how much the patient was treated with respect, dignity and kindness. The answers to the questions

Table 4. Distribution and differences of the symptom scales before and after LCP-I implementation.

	Before (n = 46)		After (n = 33)		Difference		p value
	n	%	n	%	OR	(95% CI)	
Patients with pain	40	93.0	30	90.9			
Treatment for pain received[a]	36	97.3	28	100			
Pain relieved much or very much[b]	19	59.4	17	65.4			
Overall control of pain	22	61.1	20	69.0	1.4	(0.5–4.0)	0.514
Patients with breathlessness	37	82.2	28	84.8			
Treatment for breathlessness received[a]	31	91.2	21	95.5			
Breathlessness relieved much or very much[b]	7	24.1	7	36.8			
Overall control of breathlessness	15	37.5	12	48.0	1.5	(0.6–4.2)	0.408
Patients with nausea – vomiting	14	31.1	5	15.2			
Treatment for nausea – vomiting received[a]	7	58.3	2	66.7			
Nausea – vomiting relieved much or very much[b]	2	40.0	–				
Overall control of nausea – vomiting	33	80.5	28	90.3	2.3	(0.6–9.5)	0.261

LCP-I: Italian version of the Liverpool Care Pathway; CI: confidence interval; OR: odds ratio.
[a]Analysis limited to the sub-group of patients with the symptom.
[b]Analysis limited to the sub-group of patients with the symptom who received a treatment.

of this scale are largely influenced by the quality of the work of nurses and health assistants. Nursing staff in the focus groups[14] reported a feeling of frustration with regard to their work, but after the LCP-I implementation, there was a consensus concerning the improvement in communication within the ward team. It is reasonable that this improvement in communication between professionals resulted in a better quality of care.

This study does not show a significant improvement in symptom control. Other studies carried out in hospitals have suggested benefits of using the LCP to improving symptom management,[12–15] but none had assessed symptom control as reported by family members. During the focus groups,[14] the professionals reported feeling more confident with pain management. Unfortunately, this positive self-assessment did not result in significant improvement in the management of pain, breathlessness and nausea-vomiting. These results point to the importance of collecting outcome data directly from family members or where possible patients, as health professionals may under-report symptoms.[25] It is possible that the scales cannot detect, through the proxies, the prevalence and the distress caused by these physical symptoms.

The implementation of the LCP in Italy had some differences from the United Kingdom and other settings. In particular, we did not use 'facilitators' but instead used professionals from PCTs who were well trained and already working in palliative care. We could not afford the resources of additional facilitators but also felt that it was important that the LCP-I training was carried out by established teams who were well known to the wards. We placed a great emphasis on training, with a 12-h course, which was mandatory for all professionals of the ward before

they could start to use LCP-I clinical documentation. Although we followed in general the 10-steps proposed by LCP, the LCP-I process of implementation developed a manual with specific goals to be achieved step by step, aimed to make the programme more replicable and the introduction more reliable.

This study has important limitations. First, as discussed in the previous methodological article,[17] an uncontrolled before–after study design is, by definition, affected by a selection bias. Our findings show that some characteristics, mainly gender and time in hospital and ward, are slightly different. More importantly, a higher proportion of family members were interviewed face to face in the before sample. Conversely, the magnitude of the observed differences in the Toolkit scales suggests that the improvement in quality of care after the LCP-I implementation is less likely to be attributed only to the selection bias or the play of chance. Nevertheless, caution is warranted. It is well known that observational studies are prone to overestimation of the effect sizes as compared to randomized trials.[26] These results do not substitute for randomized trial level evidence, but they do suggest that such a randomized trial should be conducted. Furthermore, they show that the LCP-I programme is producing similar or greater effects than those found in other evaluations of the LCP using similar study designs.[15,16]

Second, this study was performed in a single hospital where the LCP-I was implemented by the PCT that translated and introduced the LCP programme in Italy. Much of the research on the LCP has been conducted by centres responsible for LCP dissemination in their country. It is questionable whether the LCP-I programme may be replicated by other centres. As this study is preliminary to a ran-

domized phase III trial, where many PCTs have to be trained to implement the LCP-I programme in hospital wards, this point is crucial. The LCP-I is a typical complex intervention. The results of studies assessing the effectiveness of complex interventions (i.e. psychotherapy) show that part of the variability in outcomes can be attributed to the way the complex intervention was delivered.[27,28] One of the major challenges in a multi-centre trial aimed at assessing the effectiveness of the LCP-I programme will be ensuring that the intervention is delivered optimally by all PCTs in all the centres.

Third, we cannot exclude that the recall bias inherent in the approach used for assessment might have biased the results. The compliance is rather high in both the samples, although a higher proportion of family members was interviewed face to face in the 'before sample'. This difference should not have affected the direction of the effect, as in both samples the 'face-to-face' interviews were associated with higher Toolkit scores.

Fourth, our data are limited to the outcomes of patients who died during the period before or after LCP-I implementation. We used an intention-to-treat approach. We included all patients irrespective of whether they were 'on' or 'not on' the LCP-I, and of the duration of time spent in ward. Furthermore, we do not have data on patients who did not die during the study period in those wards – to check that their care was not adversely affected.

In conclusion, the results from this study found that the LCP-I programme is feasible and replicable in the Italian context. Our procedures of assessment were appropriate and usable, and the cluster approach was successful. The results provide the first robust data collected from family members, in any reasonably sized sample, of a potential clinically significant improvement in some aspects of quality of care – in particular respect, kindness and dignity, family emotional support, self-efficacy of the family and coordination of care. However, it did not show effect for symptoms control, which suggests areas for further innovation and development. These promising results support the need for multi-centre cluster randomized controlled trial of the LCP-I.[29]

Acknowledgements

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

Funding

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