

Supportive Care

Development and Validation of Palliative Care Bundle for Advanced Gallbladder Cancer “PALLICR”

Kusum K. Rohilla¹ C. Vasantha Kalyani¹ Amit Gupta² Sweety Gupta³ Manoj Gupta³
Nirmal Matella⁴

¹ College of Nursing, All India Institute of Medical Sciences, Deoghar, India

² Department of Surgery, All India Institute of Medical Sciences, Rishikesh, India

³ Department of Radiation Oncology, All India Institute of Medical Sciences, Rishikesh, India

⁴ Art of Living, Rishikesh, India

Address for correspondence Kusum K. Rohilla, Nursing Tutor, All India Institute of Medical Sciences, Deoghar 814152, Jharkhand, India (e-mail: kus2211@gmail.com).

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Abstract



Kusum K. Rohilla

Keywords

- ▶ development
- ▶ validation
- ▶ palliative care bundle
- ▶ advanced gallbladder cancer
- ▶ PALLICR

Background The aim of this study was to develop and validate a comprehensive palliative care bundle “PALLICR” for advanced gallbladder cancer (GBC) patients.

Materials and Methods The present study was an exploratory study with instrument validation design which was conducted at All India Institute of Medical Sciences, Rishikesh, India. A total of 25 advance cancer patients were selected using the purposive sampling technique.

Results The newly developed PALLICR bundle consists of six items under three subfactors, that is, functional recovery, resilience, and quality of life. The final version of bundle with six items of PALLICR bundle was validated and showed a good fit to provide palliative care to advanced GBC patients. Standardized scales, that is, palliative care outcome scale, European Organization for Research and Treatment of Cancer quality-of-life scale for patients and caregiver strain index for caregivers were used for evaluation of PALLICR bundle effectiveness.

Conclusion PALLICR bundle is valid and reliable methods to provide palliative care to advanced GBC patients.

Introduction

World Health Organization (WHO) stated palliative care as integrated and people-centered care that alleviates the suffering of a cancer patient.^{1–3} GLOBOCAN 2018

reported that gallbladder cancer (GBC) accounts 1.2% of global cancer diagnoses and death rate is 1.7%, which is very high.^{4–6} GBC had devastating impact on physical, social, and psychological domains.^{7–10} The present focused was to develop and validate a palliative care bundle

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“PALLICR” for providing palliative care to advance GBC patients.

Materials and Methods

Study Design

The present study was an exploratory survey using instrument validation design conducted on 25 advanced GBC patients at All India Institute of Medical Sciences (AIIMS), Rishikesh, India. Five phases of palliative care bundle development, that is, items identification, construction validity and reliability testing, training of health professionals, and implementation and evaluation of palliative care bundle.

In Phase I, item development was done by extensive literature search in PubMed and Embase with MeSH terms, that is, “Palliative” OR “Palliative care” AND “Gallbladder cancer” OR “GBC” OR “Advance gallbladder cancer” AND “Patients” OR “Person” for search in-depth information for palliative care needs were obtained. Inclusion criteria for articles were English language, palliative care for any advanced cancer patients, and advanced GBC patients. Exclusion criteria were editorial reviews and opinion articles. Studies following PRISMA guidelines were selected and total 10 statements for palliative care for advanced GBC patients were identified (→Fig. 1) Face validity was obtained by 11 experts, that is, four palliative care physicians, three palliative care nurses, two social workers, and two advanced GBC patients. They did qualitative assessments for relevance of wording, difficulty, and suitability of each item by using a five-point Likert scale from 1 to 5 (1 = completely unnecessary and 5 = completely necessity), and impact score was calculated (impact score = frequency [%] × necessity). Items with >1.5 score were retained. Content validity was obtained by using qualitative and quantitative methods and content validity was done. Qualitative assessment done by experts validated each item for its wording, word placement, and grammar. Quantitative assessment includes content validity

ratio (CVR), content validity index (CVI), and kappa values. CVI evaluates item appropriateness and CVR investigates the needs of items. For CVI evaluation, using the “Lawshe table,” the initial draft was submitted to 11 experts (4 palliative care physicians, 3 palliative care nurses, 2 social workers, and 2 advanced GBC patients). Items scores >0.571 were retained for the study. The initial draft was submitted to 11 experts for CVR evaluation, who rated its appropriateness on a five-point Likert scale (5 = highly relevant, 4 = relevant but requires modification, 3 = relevant but requires minor revisions, 2 = somewhat relevant but requires major changes, and 1 = not relevant). Items with values >0.78 scores were retained. Kappa value was calculated to get an interrater agreement. Kappa values act as a supplement to CVI because it provides more information about the degree of agreement. Kappa coefficient values >0.74, 0.73 to 0.60, and 0.59 to 0.40 indicate excellent, good, and fair agreement, respectively. A second draft with six statements for the PALLICR bundle was developed.

In Phase II, construct validity for factor analysis was done in a pilot study. Before factor analysis, Bartlett’s test and Kaiser–Meyer–Olkin’s (KMO) test were done for sample adequacy for factor analysis. A Bartlett’s test significant value of less than 0.05 indicates that items have a valuable correlation according to the correlation matrix and KMO test value >0.7 indicates an adequate sample size. Finally, researchers obtained eigen values of >1, which indicates the correct number of factors and screen plot. Reliability was checked by Cronbach’s α coefficient for internal consistency was measured and α value of ≥ 0.7 indicates acceptable internal consistency. To determine overlapping factors, Cronbach’s α value was reassessed by using split-half reliability measurement and deleted item with lowest internal consistency. Test–retest reliability was also calculated to determine the stability of the PALLICR bundle. Thus, developed PALLICR bundle consists of Information, Education, Communication (IEC) problem-solving counseling for patients as well as caregivers, symptom management, care of percutaneous trans-hepatic biliary drainage (PTBD) tubes, and bhasrika pranayama for patients as well as caregivers with six statements with three important factors, that is, functional recovery, resilience, and quality of life. Thus, palliative care bundles are standardized, straightforward sets of evidence-based practices.

In Phase III, after selecting pilot wards, senior nursing officers (SNOs) and pilot staff were trained and discussed proposal, intervention, and desired outcomes. Three members from each pilot ward and link person were trained. Specialist person and clinical staff of pilot wards asked to give written feedback and opinion and their comments were incorporated based on collective agreement. In Phase IV, PALLICR bundle was implemented on 25 advanced GBC patients for 15 days and their data were collected from each patient. In Phase V, evaluation was done by using standardized scales to evaluation PALLICR bundle effectiveness.

Patients

Twenty-five advanced GBC patients using total enumeration technique were selected in department of surgery and radiation oncology wards of AIIMS, Rishikesh, India from August to

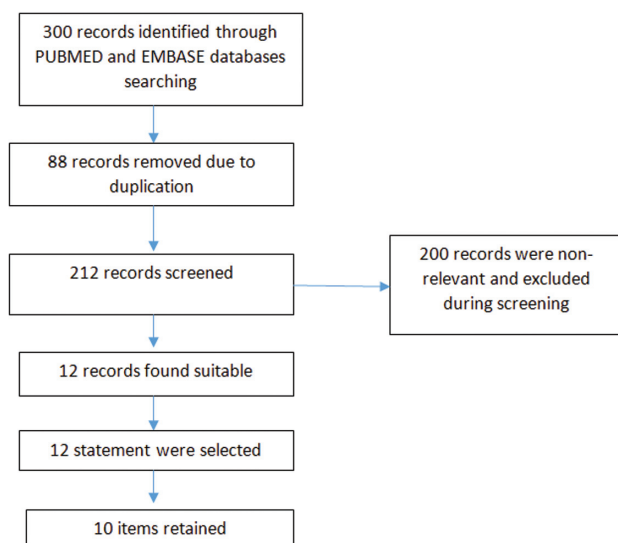


Fig. 1 Flow diagram for selection of items based on PRISMA guidelines.

Table 1 Biodemographic of patients of surgical ward II and radiation oncology

S. No.	Variables	Options	Frequency	Percentage
1	Age (y)	30–40	10	40
		40–50	15	60
2	Gender	Male	05	20
		Female	20	80
3	Education qualification	Senior secondary	10	40
		Graduate	15	60
4	Income (INR/mo)	<20,000	10	40
		>20,000	15	60
5	Caregiver relationship	Spouse	20	80
		Children	05	20
6	Stage of disease	Stage III	15	60
		Stage IV	10	40
7	Eastern Cooperative Oncology Group (ECOG)	0	04	16
		1	10	40
		2	11	44
8	Department	Surgery ward-II	15	60
		Radiation oncology	10	40

December 2019 (→ [Table 1](#)). Inclusion criteria were patients with advanced GBC, age older than 18 years, and willing to participate in studies. Exclusion criteria including patients with a diagnosis of stages I and II GBC were excluded.

Treatment

Palliative care bundles for patients and caregiver mainly include IEC problem solving counseling and bhastrika pranayama (five cycle/day) each day. For patient, symptom management and care of PTBD care were done on each day.

Assessment

Palliative care bundles were administered to 25 patients and their caregivers for next 15 days and did an evaluation of palliative care bundle every day using standardized scales, that is, palliative care outcome scale (POS),¹¹ European Organization for Research and Treatment of Cancer (EORTC) quality-of-life scale,¹² and caregiver strain index (CSI).¹³

Statistical Analysis

Data analysis was done by using IBM SPSS version 23.0. Frequency, percentage, CVR, CVI, and kappa values were calculated to assess factors.

Ethical Considerations

This research project was ethically approved by the institute ethical committee of AIIMS, Rishikesh (AIIMS/IEC/19/912). Trial is registered under CTRI number “CTRI/2021/01/030791”. Written informed consent was obtained from each study participant and their caregivers.

Results

Face validity of 10 statements of PALLICR bundle and CVI and CVR values of statement were acceptable (more than 0.78 and 0.57, respectively). Kappa statistics for all statements were also acceptable (0.83–1.00) (→ [Table 2](#)). For reliability,

Table 2 Factor matrix of PALLICR bundle for palliative care

S. No.	Group	Care	Components		
			CVI	CVR	Kappa value
1	Patient	IEC problem solving counseling	0.88	0.68	0.88
		Symptom management	0.86	0.66	0.86
		Care of PTBD tube	0.82	0.72	0.85
		Bhastrika pranayama (five cycle/d)	0.80	0.70	0.84
2	Caregiver	IEC problem solving counseling	0.92	0.82	0.86
		Bhastrika pranayama (five cycle/d)	0.94	0.80	0.84

Abbreviations: CVI, content validity index; CVR, content validity ratio; PTBD, percutaneous transhepatic biliary drainage.

Cronbach's α value was calculated. Value more than 0.87 suggests scale has good internal consistency. Karl Pearson's correlation coefficient with PALLICR bundles ranges from 0.46 to 0.96. So, two statements were dropped from the PALLICR bundle and a total of six statements were included in the final draft. We applied the PALLICR bundle to 25 patients in pilot wards for 15 days. The reliability of the six statements was measured in half and the calculated value was 0.96.

During implementation of PALLICR bundle, Plan-Do-Study-Act cycles were followed. It mainly consists of three cycles: Cycle 1, enrollment; Cycle 2, training and education; and Cycle 3, implementation and evaluation.

Enrollment of pilot staff and SNOs from pilot wards was approached and enrolled to participate in this project. We explained them in detail regarding the palliative care bundle, its importance, and the project aims. Communication with the head of the department and consultants is done by face-to-face interview as well as e-mail regarding the project proposal and its benefit to patients and caregivers. Clinical staff in pilot wards were informed regarding the PALLICR bundle and if they had personal interest, they could become link people for the PALLICR project. Introductory meetings were conducted with other people to discuss their role in PALLICR bundle development, which includes assisting in development, testing, and relevant documentation.

Training and education of pilot staff and link person for five sessions were planned for pilot ward staff members and link person by face-to-face session on PALLICR bundle. During their education sessions, the main topics of discussion were the aim and impact of PALLICR, the role of Pilot Staff (PS), best practice in PALLICR bundle, development of PALLICR bundle, evaluation methods, data entry, and staff contribution. After attending these sessions, the PS and link person would have provided positive feedback regarding the PALLICR bundle.

Implementation and evaluation of PALLICR bundle was given to all pilot staff of both wards. They were asked to complete PALLICR bundles in 15 days on 25 patients. Feedback was gathered from the pilot staff and the link person. A minor alteration was incorporated into the PALLICR bundle. Data collection tools, that is POS ([Fig. 2](#)), EORTC quality-of-life scale ([Fig. 3](#)), and Zarit Burden Interview (ZBI) Scale ([Fig. 4](#)) for monitoring of efficiency of palliative care bundle for advanced GBC patients and caregivers. After testing

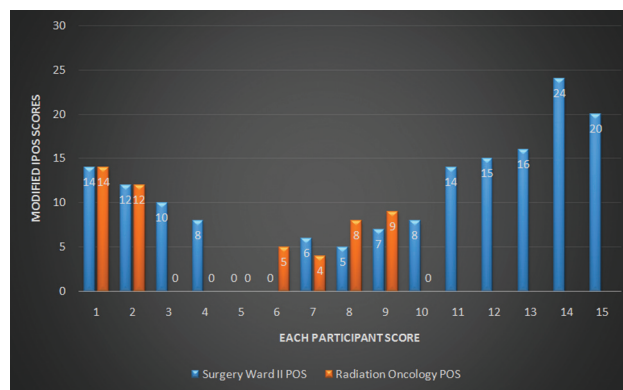


Fig. 2 Palliative care outcome scales (POSs).

documents of the PALLICR bundle and data collection tool, the process took about a month. As a result, the researchers discovered that the PALLICR bundle is a dependable, feasible, and validated good fit for providing palliative care to any advanced GBC patient.

Discussion

The goal of this study was to create and test an effective PALLICR bundle for maintaining functional recovery, resilience, and quality of life in advanced cancer patients. Face and content validities were checked by experts and construct validity was determined by CVI and CVR. The internal consistency of the PALLICR bundle was measured to check reliability.

An important pre-requisite for development of the PALLICR bundle is content validity, which is to assess relevancy and degree of appropriateness of an instrument.¹⁴ In the present study, we checked the content validity of the first draft of PALLICR bundle based on 11 expert feedback. In the validation study, the face validity of the PALLICR bundle is an essential step, so we have given the PALLICR bundle to participants who were close attributes to the target population. As suggested, necessary corrections were made.

In the present study, we extracted the final PALLICR bundle with six statements and three important factors. i.e., Factor I is intervention for functional recovery of advanced cancer patients, Factor II is intervention for resilience, and Factor III is intervention for quality of life.

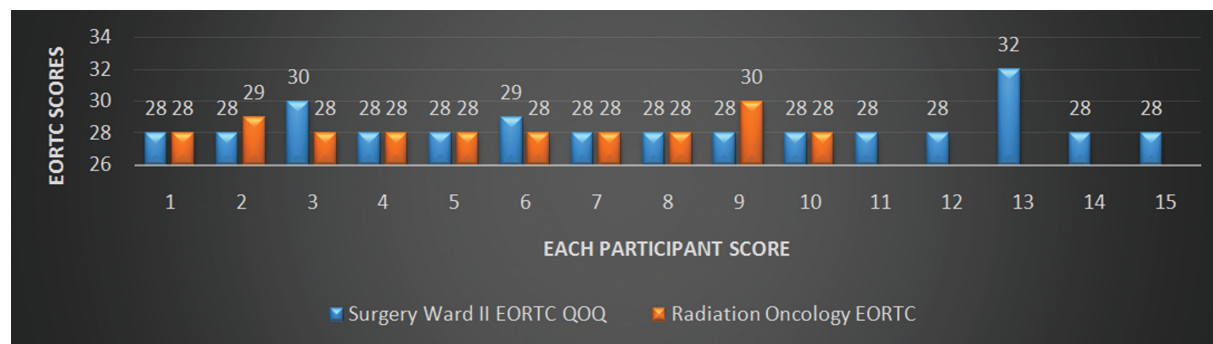


Fig. 3 European Organization for Research and Treatment of Cancer (EORTC) quality-of-life scales.

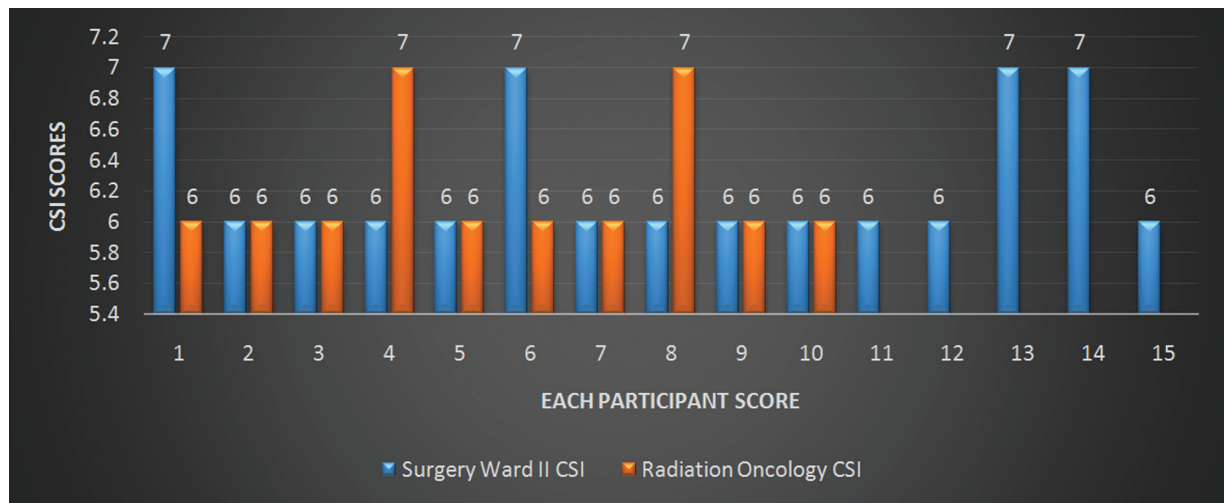


Fig. 4 Caregiver strain index (CSI) scores.

Another important dimension is the homogeneity of statements during the development of a PALLICR bundle. The Cronbach's α for overall PALLICR bundle was 0.88 and for each of the three factors, it ranged from 0.82 to 0.88, which showed good internal consistency for newly developed PALLICR bundles. Based on the final PALLICR bundle, functional recovery, resilience, and quality of life of advanced GBC patients can be maintained. Therefore, the present study verified the content, face, and construct validity and reliability, that is, stability and internal consistency of PALLICR bundle as per the Indian context. Therefore, a continuous assessment and application of the PALLICR bundle shows good results of palliative care being delivered to patients. Developed PALLICR bundles are now embedded in routine practice for advanced GBC patients at AIIMS, Rishikesh, India.

Limitations

After conducting this project, several lessons were learned: *Training and education:* As the PALLICR bundle was new to the arena identified by researchers, an extensive review of the literature was required to prepare content areas for training and education. Five regular training sessions were kept for SNOs, pilot staff, and link persons in pilot wards. PALLICR bundle details were displayed on the educational board and handouts were issued in each pilot ward which showed the strength of this study. This project was intended to incorporate new practices into existing ways of operating, so important discussions were held at AIIMS, Rishikesh, India, after each training session with pilot staff and link person to encourage palliative care. The PALLICR bundle is a positive means of enhancing palliative care and a newer method of delivery of palliative care delivery. It is not seen as any additional work or burden to the palliative care team and is only identified as "additional information for bundle of care."

Regular feedback: Regular feedback was difficult to achieve due to shifting work of all clinical staff. So, pilot staff

availability was ensured and their information was considered the final demand for change in clinical practice. On a regular basis, corresponding e-mail, ward meetings, and notices were used as means of communication for sharing information for any improvement or change in practice.

Other Challenges: At present, there is no such well-defined palliative care bundle "PALLICR." So, researchers faced a lot of problems giving them a well-defined shape to it. These bundles try to cover all domains of palliative care and it is very beneficial for patients as well as their caregivers.

Conclusion

Till date, there has been no standardized palliative care, so palliative care varies from individual to individual. Validated palliative care bundles were extracted from this research by the researchers. This standardized palliative care bundle is used by palliative care staff in the palliative care units. In this palliative care bundle, researchers used standardized data collection tools to capture comprehensive data of patients, which is again a positive point of the study. Research project, which was started in two pilot oncology wards, further needs more and more testing. So further, a better version of the PALLICR bundle could come out of this. The data collected from the "PALLICR" bundle showed robust and positive results. However, at this stage, statistically, we demonstrate that the PALLICR bundle helps in the improvement of palliative care outcomes and quality of life of an individual and their caregivers. The PALLICR bundle is an integral part of palliative care for advanced GBC patients at AIIMS, Rishikesh, India.

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Conflict of Interest

None declared.

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