INTRODUCTION

Chemotherapy is one modality for cancer treatment and customarily delivered in a hospital. Ambulatory home-based chemotherapy was initiated in the 1970s in Western countries (DeMoss, 1980). Today, this healthcare service system is implemented worldwide, based on findings demonstrating its effectiveness, safety, cost savings, convenience, patient satisfaction and improved quality of life. Additionally, this approach reduces the length of hospital stay and the risk of hospital-acquired infections (Keshvani et al., 2019).

The equipment used for home chemotherapy administration is either an electronic or a non-electronic infusion device. The elastomeric infusion pump is a non-electronic device that requires no programming and is suited for the home setting owing to its small size, light weight, safety, accuracy, comfort, simplicity of use, ease of fluid filling and lack of maintenance cost (Broadhurst, 2012). Chemotherapy infusion is driven by pressure created by the stretched elastomeric membrane; the flow rate is generated by the pressure gradient across the flow restrictor and the fluid viscosity (Skryabina & Dunn, 2006). Moreover, the patient’s body temperature, type

RESEARCH ARTICLE

Evaluation of adverse events and health-related quality of life in patients with colorectal cancer receiving ambulatory home-based chemotherapy in Thailand

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Abstract

Aims: To compare adverse events and health-related quality of life in ambulatory home-based chemotherapy with those in inpatient.

Design: Prospective non-randomized observational study.

Methods: Participants were divided into two groups according to patients’ preference receiving chemotherapy.

Results: Sixty-four participants were enrolled in the inpatient, and 111 were in an ambulatory home-based chemotherapy. The frequency of anaemia, neutropenia and thrombocytopenia was significantly higher in inpatient group than in ambulatory home-based chemotherapy group (p < .001, <.001 and .002, respectively). Nausea, mucositis, and fatigue were more common in ambulatory home-based chemotherapy group than in inpatient group (p < .001, .022, and .005, respectively). Patients in the ambulatory home-based chemotherapy group showed higher social well-being (SWB) scores than inpatient group (coefficient 1.92, 95% confidence interval [CI] 0.65 to 3.19, p .003).

KEYWORDS adverse events, ambulatory home-based chemotherapy, colorectal cancer, health-related quality of life, inpatient

1 | INTRODUCTION

Chemotherapy is one modality for cancer treatment and customarily delivered in a hospital. Ambulatory home-based chemotherapy was initiated in the 1970s in Western countries (DeMoss, 1980). Today, this healthcare service system is implemented worldwide, based on findings demonstrating its effectiveness, safety, cost savings, convenience, patient satisfaction and improved quality of life. Additionally, this approach reduces the length of hospital stay and the risk of hospital-acquired infections (Keshvani et al., 2019).
of venous access and position of reservoir influence the flow rate (Broadhurst, 2012).

2 | BACKGROUND

According to GLOBOCAN 2018 data, the incidence of colorectal cancer is rising and it is now the fourth most commonly diagnosed cancer worldwide (Rawla et al., 2019); however, early detection and advanced treatment with multiple modalities have reduced the mortality rate. Fluorouracil (5-FU) combined with oxaliplatin/leucovorin (mFOLFOX6) and irinotecan/leucovorin (FOLFIRI) is a standard treatment regimen in patients with colorectal cancer in an adjuvant or palliative setting. Traditionally, in Thailand, a 5-FU combination regimen with continuous infusion requires hospitalization for 2–3 days. Therefore, most general hospitals have an overload of patients and a shortage of resources and manpower, impeding the accessibility to chemotherapy. Successful cancer treatment requires the interaction of several factors including hospital infrastructure, a multidisciplinary team (MDT), the healthcare service system, new efficient drugs, financial resources and patient compliance. In late 2015, an MDT composed of medical oncologists, nurses and pharmacists initiated the Ramathibodi home-based chemotherapy model (RHCM) as a new healthcare service system in Thailand. The aim of the RHCM is to enhance the quality of healthcare treatment services and the quality of life in patients with cancer.

Health-related quality of life (HRQOL) is a strong independent predictive factor in patients with colorectal cancer (Sharma et al., 2013). HRQOL is affected by disease status and cancer treatment and encompasses physical, psychosocial, environmental and spiritual aspects (Temiz & Durna, 2020). An increased number of chemotherapy cycles and increased severity of adverse events reduces HRQOL (Gozdziewicz et al., 2017). An ambulatory home-based chemotherapy setting can improve patient’s mental and spiritual health via receiving support from family, having a greater sense of control over treatment and the familiar home environment. Therefore, this setting might alleviate adverse events and consequently improve quality of life (Lee et al., 2010). Moreover, ambulatory home-based chemotherapy is a patient-centred care that offers benefits for patient-reported outcomes in terms of acceptability, feasibility, safety, cost savings and patient satisfaction (Borras et al., 2001; Cool et al., 2018; Crisp et al., 2014; Evans et al., 2016; Joo et al., 2011; Kelly et al., 2004; Kulthanachairojana et al., 2020; Lee et al., 2010; Lippert et al., 2017).

However, data about the effect of ambulatory home-based chemotherapy on patient HRQOL are still controversial: some studies have shown benefits whereas others have not (Borras et al., 2001; Hinz et al., 2018; Lee et al., 2010).

2.1 | Aims

According to a new paradigm of chemotherapy administration at home in Thailand, in this study, we aimed to compare patient HRQOL scores and common adverse events in an ambulatory home chemotherapy (AC) setting with those of patients in an inpatient setting (inpatient department, IPD).

3 | METHODS

3.1 | Design

This was a prospective non-randomized observational study.

3.2 | Participants

Patients were invited to participate in the study based on the following inclusion criteria: (a) diagnosed with colorectal cancer; (b) older than 18 years with controlled underlying disease; (c) treatment with a 5-FU regimen by continuous infusion in combination with either oxaliplatin or irinotecan; (d) good performance status [PS, ≤2]; (e) good compliance with follow up in the study; and (f) no cognitive impairment.

3.3 | Data collection

3.3.1 | Study protocol

Participants who met the eligibility criteria were enrolled in one of two groups, according to their preference. Group A underwent traditional chemotherapy at the hospital (IPD) and group B received chemotherapy in an ambulatory home-based chemotherapy setting (AC). Participants in group B had an implantable port inserted for chemotherapy administration; these patients had to reside near a hospital in the Bangkok area. For patients being treated at home, 24-hr telephone support would be available to communicate with a nurse case manager. Additionally, for the first three cycles, a nurse case manager telephoned patients in group B to assess whether they had experienced any adverse events and how device functioned in the patient’s home. We collected and evaluated demographic data, common adverse events and HRQOL using the Functional Assessment of Cancer Therapy Colorectal (FACT-C) questionnaire (Thai version) for all participants. The data were collected at the time of enrolment, at 8 weeks and at the end of treatment (24 weeks).

3.3.2 | Chemotherapy protocol

Participants in group A required hospitalization for the administration of chemotherapy, for 2–3 days every 2 weeks. Participants in group B received oxaliplatin or irinotecan concurrent with leucovorin for a short infusion of 3–4 hr, followed by 5-FU bolus injection and continuous infusion using an elastomeric infusion pump via the
implanted port at the hospital ambulatory unit; patients then used the infusion pump at home continuously for 50 hr (Figure 1).

### 3.3.3 | Instruments

**FACT-C questionnaire**

Patient HRQOL was evaluated using the FACT-C questionnaire version 3 (Thai). The FACT questionnaire was developed by Cella et al. (1993); it was generated from the Functional Assessment of Cancer Therapy-General (FACT-G) and Colorectal Cancer Subscale (CCS) (Ward et al., 1999). The FACT-C has been translated into several languages, including Thai (Ratanatharathorn et al., 2001; Webster et al., 2003). It has been used in clinical settings worldwide and has acceptable psychometric properties for construct validity and reliability, internal consistency; alpha 0.85–0.91 (Pullmer et al., 2014; Ward et al., 1999). This self-administered questionnaire with a four-point Likert scale is composed of four core domains and a 36-item subscale: physical well-being (PWB), Seven items (score 0–28); social well-being (SWB), Seven items (score 0–28); emotional well-being (EWB), Six items (score 0–24); and functional well-being (FWB), Seven items (score 0–28). The CCS has nine items; two items were not currently scored; thus, scores were 0–28. The three main outcomes of HRQOL were assessed using the FACT-C Trial Outcome Index (TOI), FACT-G and FACT-C. The sum of scores in the domains PWB, FWB, and on the CCS comprise the FACT-C (TOI) (score 0–84) which indicates physical condition. The sum of the four core domains of PWB, SWB, EWB and FWB comprise the FACT-G (score 0–108). The sum of these core domains and the CCS comprise the FACT-C total (score 0–136). A higher score indicates better HRQOL.

**Common terminology criteria for adverse events (CTCAE) version 4**

Adverse events were measured using CTCAE version 4, which is the most commonly used instrument to measure adverse events in clinical trials and clinical practice in oncology settings.

### 3.3.4 | Ethics

The study was reviewed and approved by the Regional Human Research Ethics Committee. All participants were informed about the aim of the study and the methods, risks and benefits. Written informed consent was obtained from all participants.

### 3.3.5 | Data analysis

**Statistical analysis**

Due to limited data of FACT-C score in chemotherapy treated colorectal cancer patients, Hee Jung Yoo and colleague (Yoo et al., 2005) reported FACT-C score in postoperative CRC patients in which 70% of patients in this study was received adjuvant chemotherapy post-operation. Therefore, FACT-C score at 6 months (mean [SD] of 90.84 [20.71]) postoperation was used as reference for FACT-C score (IPD group) in this study. We set difference of FACT-C between IPD and AC group at 10 to be clinically significant. The study was planned to enrol patients in 1:2 ratio for IPD and AC group, respectively. With type I error of 5% and power of 80%, 52 and 104 patients were needed for IPD group and AC group, respectively.

Baseline characteristics were described using mean and standard deviation (SD), median and range, or number and percentage, as appropriate. Comparisons between groups A and B were conducted using the chi-square or Fisher’s exact test, as appropriate, for categorical variables and the Student t-test for continuous variables. Common adverse events are presented as number of patients and percentage. The mean ± SD of HRQOL score was summarized for each domain at baseline, during treatment and at the end of treatment. HRQOL between groups A and B was compared using mixed-effects linear regression models. Significant difference score of HRQOL domain between group A and B would be adjusted in multivariate mixed-effect linear regression model. We considered treatment setting and regimen and any factors with p-value from univariate analysis less than .1 were confounding factors that would be adjusted in the final model. All analyses were performed using Stata version 16 (StataCorp LLC, College Station). A p-value of less than .05 was considered statistically significant.

### 4 | RESULTS

#### 4.1 | Patient characteristics

A total of 175 patients with colorectal cancer in Ramathibodi Hospital, Mahidol University, from December 2015 to November 2016 were enrolled in this study. Of these, 64 participants were included in group A (inpatient group) and 111 were included in group B (ambulatory home-based chemotherapy). Most participants (90%) had good ECOG performance status of 0–1. More than 50% of participants had advanced-stage disease at diagnosis and 45% had...
recurrent disease. Most participants received an oxaliplatin-based regimen (67%). Baseline characteristics were well balanced between groups, except age. Participants in group A were significantly younger than those in group B, with mean age 57.7 ± 12.6 years and 62.2 ± 9.9 years (p = .011), respectively (Table 1).

### TABLE 1  Demographic data

| Characteristics     | Group A (IPD) (N = 64) | Group B (AC) (N = 111) | p-value |
|---------------------|------------------------|------------------------|---------|
| Age, years          |                        |                        |         |
| (mean ± SD)         | 57.7 ± 12.6            | 62.2 ± 9.9             | .011    |
| Sex                 |                        |                        |         |
| Male                | 38 (59.4)              | 56 (50.5)              | .254    |
| Female              | 26 (40.6)              | 55 (49.5)              |         |
| Stage at diagnosis  |                        |                        |         |
| II                  | 4 (6.3)                | 4 (3.6)                | .611    |
| III                 | 23 (35.9)              | 45 (40.5)              |         |
| IV                  | 37 (57.8)              | 62 (55.9)              |         |
| ECOG-PS             |                        |                        |         |
| 0 − 1               | 58 (90.6)              | 97 (87.4)              | .517    |
| 2                   | 6 (9.4)                | 14 (12.6)              |         |
| Treatment setting   |                        |                        |         |
| Adjuvant            | 14 (21.9)              | 25 (22.5)              | .921    |
| Palliative          | 50 (78.1)              | 86 (77.5)              |         |
| Regimen             |                        |                        | .074    |
| mFOLFOX             | 39 (60.9)              | 82 (73.9)              |         |
| FOLFIRI             | 25 (39.1)              | 29 (26.1)              |         |
| Recurrent disease   |                        |                        | .310    |
| No                  | 33 (51.6)              | 66 (59.5)              |         |
| Yes                 | 31 (48.4)              | 45 (40.5)              |         |

Abbreviations: AC, ambulatory home chemotherapy; ECOG-PS, Eastern Cooperative Oncology Group-Performance Status; FOLFIRI, irinotecan, 5-fluorouracil and leucovorin; IPD, inpatient department; mFOLFOX, modified oxaliplatin, 5-fluorouracil and leucovorin; SD, standard deviation.

### 4.2  Adverse events

The incidence of common adverse events during treatment (8 weeks) was compared between groups using the CTCAE version 4. Haematologic adverse events, including anaemia, neutropenia and thrombocytopenia were significantly higher in group A than in group B (p < .001, <.001 and .002, respectively). For non-haematologic adverse events, nausea, mucositis and fatigue were more frequent in group B than group A (p < .001, .022 and 0.005, respectively). A high prevalence of neuropathy was found in both groups (48%–59%). However, most adverse events were mild to moderate and manageable (Table 2).

### TABLE 2  Comparison of haematologic and non-haematologic adverse events between groups

| Events                      | Group A (IPD) | Group B (AC) | p-value |
|-----------------------------|---------------|--------------|---------|
| Haematologic AEs (N = 63,107)|               |              |         |
| Anaemia                     | 38 (60.3)     | 15 (14.0)    | <.001   |
| Neutropenia                 | 9 (14.3)      | 5 (4.7)      | <.001   |
| Thrombocytopenia            | 6 (9.5)       | 0            | .002    |
| Non-haematologic AEs        |               |              |         |
| Nausea (N = 61,102)         | 20 (32.8)     | 71 (69.6)    | .001    |
| Vomiting (N = 61,102)       | 10 (16.4)     | 29 (28.4)    | .176    |
| Mucositis (N = 62,102)      | 15 (24.2)     | 43 (42.2)    | .022    |
| Diarrhoea (N = 61,102)      | 20 (32.8)     | 48 (47.0)    | .156    |
| Neuropathy (N = 62,102)     | 29 (46.8)     | 58 (56.9)    | .399    |
| Fatigue (N = 62,102)        | 35 (56.5)     | 76 (74.5)    | .005    |

Note: N, number of participants in group A and group B, respectively. Abbreviations: AC, ambulatory home chemotherapy; AE, adverse event; IPD, inpatient department.

### 4.3  Health-related quality of life (HRQOL)

Mean scores on the FACT-C questionnaire were compared at baseline, during treatment and at the end of treatment in both groups (Table 3 and Figure 2). The overall SWB score was significantly higher in group B than in group A (Coef. 1.92, 95% confidence interval [CI] 0.65–3.19, p <.003). Univariate analysis showed age and visit were associated with SWB score; thus, age and visit along with treatment setting and regimen were included in multivariate analysis to adjust for confounding factors. The results confirmed that SWB scores were significantly higher in group B than group A (Coef. 2.28, 95% CI 1.01–3.56, p <.001) (Table 4). Additionally, adjusted SWB score declined significantly with age (Coef. –0.07, 95% CI –0.12 to –0.03, p <.001) (Table 4). The other domains of HRQOL, the FACT-C (TOI), FACT-G and FACT-C (total), had somewhat lower scores in group B than group A, but these were not statistically significant.
These findings of this study showed that there were no major complications and adverse events were manageable in patients who received both in-hospital chemotherapy and ambulatory home-based chemotherapy. In both groups, most adverse events were of mild-to-moderate severity (grade 1–2). Haematologic adverse events including anaemia, neutropenia and thrombocytopenia were significantly higher in the inpatient group than the ambulatory home-based chemotherapy group ($p < .001$, $.001$ and $.002$, respectively): The reasons for this difference include the following. First, IPD (inpatient, group A) encompassed more patients with recurrent disease than AC (home-based, group B), and second, patients who chose to receive chemotherapy in a hospital might have had some other factors than drove them to this decision, for example, more comorbidities. The IPD group also included more cases of grade 3–4 anaemia and neutropenia than the AC group. All non-haematologic adverse events were mild to moderate (grade 1–2) but of higher frequency in the AC group. In a hospital setting, symptom and adverse event management can be promptly assessed and managed by healthcare providers.

### TABLE 3 Comparison of health-related quality of life (HRQOL) data by group

| HRQOL domain scores, mean ± SD | Group A (IPD) | Group B (AC) | Coef. (95% CI) | p-value |
|-------------------------------|--------------|--------------|----------------|---------|
| **PWB**                       |              |              |                |         |
| Baseline                      | 19.62 ± 5.38 | 20.07 ± 5.73 | 0.52 (-1.08, 2.12) | .525    |
| During treatment (8 weeks)    | 20.89 ± 4.98 | 20.43 ± 4.76 |                |         |
| End of treatment (24 weeks)   | 21.51 ± 4.74 | 19.46 ± 4.38 |                |         |
| **SWB**                       |              |              |                |         |
| Baseline                      | 18.91 ± 4.01 | 20.78 ± 3.94 | 1.92 (0.65, 3.19) | .003    |
| During treatment (8 weeks)    | 17.69 ± 3.74 | 20.59 ± 3.98 |                |         |
| End of treatment (24 weeks)   | 18.88 ± 5.40 | 20.38 ± 3.42 |                |         |
| **EWB**                       |              |              |                |         |
| Baseline                      | 17.87 ± 3.94 | 18.16 ± 4.34 | 0.31 (-1.01, 1.62) | .645    |
| During treatment (8 weeks)    | 18.68 ± 4.32 | 19.01 ± 3.94 |                |         |
| End of treatment (24 weeks)   | 19.06 ± 4.06 | 18.44 ± 4.33 |                |         |
| **FWB**                       |              |              |                |         |
| Baseline                      | 16.79 ± 5.54 | 17.84 ± 5.31 | 1.12 (-0.52, 2.76) | .181    |
| During treatment (8 weeks)    | 17.04 ± 5.70 | 17.51 ± 4.95 |                |         |
| End of treatment (24 weeks)   | 18.04 ± 5.28 | 16.12 ± 3.98 |                |         |
| **CCS**                       |              |              |                |         |
| Baseline                      | 17.10 ± 4.52 | 17.85 ± 3.88 | 0.86 (-0.44, 2.15) | .196    |
| During treatment (8 weeks)    | 18.26 ± 3.96 | 17.61 ± 4.35 |                |         |
| End of treatment (24 weeks)   | 18.99 ± 4.33 | 17.99 ± 3.77 |                |         |
| **FACT-C (TOI)**              |              |              |                |         |
| Baseline                      | 53.51 ± 12.53 | 55.69 ± 12.13 | 2.36 (-1.40, 6.12) | .219    |
| During treatment (8 weeks)    | 56.19 ± 12.41 | 55.35 ± 11.50 |                |         |
| End of treatment (24 weeks)   | 58.55 ± 12.06 | 53.50 ± 10.11 |                |         |
| **FACT-G**                    |              |              |                |         |
| Baseline                      | 73.18 ± 13.90 | 76.68 ± 14.03 | 3.84 (-0.55, 8.23) | .086    |
| During treatment (8 weeks)    | 74.50 ± 14.77 | 77.56 ± 12.89 |                |         |
| End of treatment (24 weeks)   | 77.49 ± 15.28 | 74.16 ± 12.37 |                |         |
| **FACT-C (Total)**            |              |              |                |         |
| Baseline                      | 90.28 ± 17.04 | 94.56 ± 16.92 | 4.55 (-0.74, 9.83) | .092    |
| During treatment (8 weeks)    | 92.76 ± 17.77 | 94.76 ± 15.43 |                |         |
| End of treatment (24 weeks)   | 96.49 ± 17.86 | 92.03 ± 15.38 |                |         |

Note: FACT-C (TOI): PWB+FWB+CCS; FACT-G: PWB+SWB+EWB+FWB; and FACT-C (total): PWB+SWB+EWB+FWB+CCS.

Abbreviations: AC, ambulatory home chemotherapy; CCS, Colorectal Cancer Subscale; CI, confidence interval; EWB, emotional well-being; FWB, functional well-being; IPD, inpatient department; PWB, physical well-being; SWB, social well-being; TOI, Trial Outcome Index.
FIGURE 2  (a) comparison of HRQOL scores in group A (IPD) and group B (AC). AC, ambulatory home-based chemotherapy; CI, confidence interval; HRQOL, health-related quality of life; IPD, inpatient department

| TABLE 4 | Univariate and multivariate analysis of SWB score with potential confounding factors using mixed-effects linear regression model |
|---------|--------------------------------------------------------------------------------|
| Factors                  | Univariate analysis                        | Multivariate analysis                  |
|                         | Coef. (95% CI) | p-value | Coef. (95% CI) | p-value |
| Group                  |                |          |                |          |
| A (IPD)                | Ref.           |          | Ref.           |          |
| B (AC)                 | 1.92 (0.65, 3.19) | .003      | 2.28 (1.01, 3.56) | <.001    |
| Age (mean ± SD, years) | −0.05 (−0.10, −0.01) | .023      | −0.07 (−0.12, −0.03) | .001     |
| Visit                  |                |          |                |          |
| Baseline               | Ref.           |          | Ref.           |          |
| During treatment (8 weeks) | −0.65 (−1.35, 0.05) | .068      | −1.01 (−2.10, 0.09) | .071     |
| End of treatment (24 weeks) | −0.34 (−1.19, 0.50) | .426      | −0.13 (−1.30, 1.04) | .833     |
| Stage at diagnosis     |                |          |                |          |
| II                     | Ref.           |          |                |          |
| III                    | 1.04 (−1.55, 3.64) | .430      |                |          |
| IV                     | 0.29 (−2.25, 2.83) | .820      |                |          |
| ECOG-PS                |                |          |                |          |
| 0–1                    | Ref.           |          |                |          |
| 2                      | 0.01 (−1.90, 1.93) | .990      |                |          |
| Treatment setting      |                |          |                |          |
| Adjuvant               | Ref.           |          | Ref.           |          |
| Palliative             | −0.54 (−1.81, 0.72) | .399      | −0.29 (−1.52, 0.94) | .645     |
| Regimen                |                |          |                |          |
| FOLFOX                 | 0.27 (−0.88, 1.42) | .644      | −0.24 (−1.36, 0.88) | .674     |
| FOLFIRI                | Ref.           |          | Ref.           |          |
| Recurrent disease      |                |          |                |          |
| No                     | Ref.           |          |                |          |
| Yes                    | 0.68 (−0.39, 1.75) | .215      |                |          |

Abbreviations: AC, ambulatory home chemotherapy; CI, confidence interval; FOLFIRI, irinotecan, 5-fluorouracil and leucovorin; IPD, inpatient department; mFOLFOX, modified oxaliplatin, 5-fluorouracil and leucovorin.
providers. However, in the home setting, all symptoms and adverse events were managed by patients and caregivers, who might not have strong competency to control symptoms and healthcare providers. Our findings confirmed those of previous studies showing fatigue, numbness, mucositis and nausea as the most common adverse events in colorectal cancer treatment (Borras et al., 2001; Lee et al., 2010; Pettersson et al., 2014). The prevalence of neuropathy was high in both groups (48%–59%), with no significant difference between groups (p = .399). Most patients in both groups were treated with an oxaliplatin-based regimen (61%–74%), which is the standard in colorectal cancer treatment. Similarly, a study by Pettersson et al. (2014) showed a high prevalence of symptoms in cancer treatment including numbness (64%), lack of energy (62%), drowsiness (49%) and nausea (45%). The prevalence of fatigue (57%–75%) in this study was in concordance with the findings of Pettersson et al. (2014). The frequency of severe fatigue (grade 3–4) was found to be higher in the AC group (12%) than in the IPD group (8%), which could be because there were more older patients in the AC group (mean age 62 years). This finding was supported by previous studies, with fatigue found in 16%–41% of older patients with colorectal cancer (Williams et al., 2015). Treatment-related symptoms such as fatigue, numbness, sleep disturbance, diarrhoea, stomatitis and nausea/vomiting affect the physical domain, psychological/emotional domain, functional domain and reduced overall quality of life (Gozdziewicz et al., 2017; Temiz & Durna, 2019). To maintain HRQOL in patients with cancer during treatment, healthcare providers should recognize and aim to manage all distressing symptoms related to the treatment.

In terms of HRQOL, ambulatory chemotherapy showed no benefit in terms of global HRQOL and other domains, except SWB. This finding was supported by those of previous studies (Borras et al., 2001; Cool et al., 2019; Corrie et al., 2013; King et al., 2000; Lee et al., 2010; Luthi et al., 2012). The reason for this finding can be explained as follows. First, participants in the ambulatory home-based chemotherapy setting had a higher prevalence of non-haematologic adverse events than those in the IPD setting. Previous studies have reported that treatment-related symptoms reduce overall quality of life (Gozdziewicz et al., 2017; Temiz & Durna, 2019). Second, we determined benefits according to treatment location (hospital versus home) using a quality-of-life questionnaire rather than using a more sensitive instrument for detecting changes in patients. Cool et al., (2018) stated that “it is difficult to make hard conclusions on the potential (dis)advantages of oncological home hospitalization (OHH) compared with standard hospital care. The fact is that none of the studies using validated HRQOL questionnaires observed differences in QOL between home or hospital cancer drug administration. One should also question whether the available validated QOL questionnaires are sensitive enough to detect rather small variations in QOL and if the rather small samples sizes that were used were powerful enough to detect changes.” Third, additional equipment should be used to assess benefits and patient-report outcomes such as patient’s satisfaction, feasibility, cost savings and compliance. Finally, in this study, grouping was done according to patients’ preference so bias cannot be ruled out, as we mention below. However, the ambulatory home-based chemotherapy setting had benefits in terms of patient’s satisfaction owing to the ability to conduct daily life activities, the familiar home environment, cost savings, a better relationship with nursing or care staff, and greater convenience. In Thailand, Kulthanachairojana and colleagues (2020) found that patients with colorectal cancer who completed adjuvant treatment at home had a cost savings of $1,513 per patient; this beneficial result led to a national healthcare policy of reimbursement through universal health coverage. The factors influencing patients’ preference are time-consuming hospitalization, education level, family role and employment status, which supports patients while receiving treatment (Borras et al., 2001; King et al., 2000; Lee et al., 2010; Luthi et al., 2012). The study by King and colleagues (2000) was found that 73% of patients (95% CI 59 to 86, p < .008) preferred treatment at home after experiencing both treatment locations (hospital and home), with an important reason being waiting time at a hospital. Furthermore, Lassalle et al. (2016) reported an improvement in HRQOL (84%) and stated that 98% of patients with multiple myeloma receiving bortezomib preferred home administration over hospital administration. In our experience with the RHCM, patients prefer to receive chemotherapy administration in a home setting versus a hospital setting because they are concerned about delayed treatment owing to insufficient hospital beds, time-consuming hospital services and uncertainty. However, in home settings, patients are also concerned about support from healthcare professionals, safety, device assessment and care, and control of symptoms/adverse events and control of unexpected events at home.

Home-based chemotherapy showed benefits in terms of the SWB domain whereas the other domains showed no significant difference (Coef. 2.28, 95% CI 1.01–3.56, p < .001). This finding is supported by previous studies (Crisp et al., 2014; DeMoss, 1980; Lee et al., 2010). Crisp et al. (2014) mentioned the concept of the home as a “natural habitat” that the home does not only represent a dwelling but also encompasses personal identity, security and privacy. Patients affected by cancer and cancer treatment experience a loss of control, frustration and depression. Therefore, healthcare providers should try to maintain the normal daily life of patients and their families as much as possible while treatment is ongoing; patients should also receive emotional support from their families (Gozdziewicz et al., 2017; Williams et al., 2015). A multivariate analysis showed a statistically significant decline in SWB scores with age (Coef.−0.07, 95% CI −0.12 to −0.03, p < .001). This finding was confirmed by Gozdziewicz et al. (2017) who found that participants age 40–50 years scored higher than other patients in SWB, EWB, FWB and global HRQOL, and SWB scores were lowest in participants’ age >70 years.

In summary, this study, an ambulatory home-based chemotherapy is confirmed that offers benefits for patient-reported outcomes in terms of safety and HRQOL especially SWB domain.
6 | LIMITATIONS

This was a prospective, non-randomized, observational study with a small sample size, with grouping according to participants’ preference. Therefore, selection bias cannot be ruled out.

7 | RECOMMENDATIONS FOR A FUTURE STUDIES

The initiation of this study would challenge the further studies in Thailand. Other potential and sensitive aspects about patient-reported outcomes such as safety, patient satisfaction, comorbidities, effect on caregivers, cost-effectiveness, length of hospital stay and clinical outcomes (disease-free survival and survival) should be considered as outcomes in ambulatory home-based chemotherapy in further studies. Important, further studies with an appropriate study design and a greater number of potential outcomes should be conducted, to confirm the benefits of ambulatory home-based chemotherapy in Thailand.

8 | CONCLUSION

The results of this study emphasized the benefits of ambulatory home-based chemotherapy for patients with colorectal cancer in terms of safety and HRQOL with respect to SWB. This new service option was proven to be useful for patients and caregivers, healthcare providers and a new paradigm in the healthcare service system in my hospital, which can be expanded to public hospitals across Thailand. Therefore, healthcare providers would provide education and empower cancer patients and their caregivers to enhance competency for caring themselves and device at home.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization, design and data collection of the study. The manuscript was written by SS and edited by PC. The final version was approved by all authors.

ETHICAL APPROVAL

The study was approved by Regional Human Research Ethics Committee (no. MURA2015/675), the Faculty of Medicine Ramathibodi Hospital, Mahidol University.

CLINICAL TRIAL REGISTRATION NUMBER

TCTR identification number is TCTR20201117001.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the first author and corresponding author upon reasonable request.

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