



# Effect of continuity of care on anticoagulant therapy and quality of life after heart valve replacement: a systematic review and meta-analysis

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**Background:** Valvular heart disease (VHD) is a leading cause of heart diseases and death, and heart valve replacement (HVR) plays a fundamental role in treating valve disease and improving the function of valves. The lack of continuity of care (CC, also known as transitional care) for postoperative patients after discharge often results in a variety of complications, bringing severe pain to the patients and diminishing their quality of life.

**Methods:** We systematically searched for relevant randomized controlled trials (RCTs) in Cochrane databases, PubMed, Embase, CINAHL, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chongqing VIP, and Wanfang Data. The methodological quality of the included articles was assessed using the Cochrane Handbook for Systematic Reviews of Interventions. The meta-analysis was conducted with RevMan 5.2 software.

**Results:** A total of 14 RCTs (involving 1,825 patients), all in Chinese language, were included in the analysis, including 920 patients in the CC group and 905 patients in the control group (receiving the routine care). Meta-analysis showed that, compared with the control group, the CC group had significantly higher anticoagulation therapy adherence [RR =1.36, 95% CI: (1.25,1.48), P<0.00001], higher awareness of anticoagulation [RR =1.14, 95% CI: (1.09, 1.18), P<0.0001], and lower incidences of anticoagulation complications and adverse events [RR =0.24, 95% CI: (0.17, 0.35), P<0.00001]. In addition, the 5 domains reflecting quality of life including physical domain [MD =2.38, 95% CI: (1.30, 3.46), P<0.0001], psychological domain [MD =2.92, 95% CI: (1.47, 4.37), P<0.0001], levels of independence [MD =4.03, 95% CI: (1.04, 7.01), P=0.008], social relationships [MD=2.56, 95% CI: (1.81, 3.32), P<0.00001], and environment [MD =4.15, 95% CI: (1.16,7.14), P=0.007] were also significantly improved.

**Discussion:** Our results showed CC can effectively improve patients' anticoagulation therapy adherence and raise their awareness about medications, reduce the incidences of complications and adverse events, and thus improve the patients' quality of life. However, only a limited number of high-quality RCTs were included in our current analysis, and studies with more rigorous designs are warranted to further validate the impacts of CC on anticoagulation therapy adherence and quality of life after HVR.

**Keywords:** Continuity of care; anticoagulant therapy; quality of life; meta-analysis

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## Introduction

Valvular heart disease (VHD) is a series of clinical syndromes caused by anatomical or functional abnormalities of the heart valves and their surrounding tissues due to various acquired pathologies or congenital developmental malformations, which result in single or multiple valve stenosis or incomplete closure. VHD is considered to be a major cause of heart disease and death (1). The incidence of VHD is 2.5 to 3.2 per 1,000 person-years in China (2). Heart valve replacement (HVR) is a surgical procedure to restore the normal function of heart valves by replacing the damaged ones with artificial heart valves (3). Continuity of care (CC) refers to the extended nursing services offered by specific medical personnel to the discharged patient after HVR. If necessary, home follow-up services can be arranged to enable the medical staff to offer consultations to the patients (4-6). It has been found that, due to the lack of knowledge on anticoagulation and nursing instructions, the postoperative patients after discharge often suffer from a variety of complications, such as thromboembolism, angina pectoris, pulmonary infection, and bleeding, bringing severe pain to the patients and diminishing their quality of life (7). In China, conventional nursing education is typically delivered upon discharge. Although the benefits of CC in VHD patients have been demonstrated in literature, its efficacy remains controversial due to the limited inputs from health care professionals. The aim of this study was to investigate of impacts of CC on anticoagulant therapy and quality of life after HVR and thus inform the promotion of CC in clinical settings.

We present the following article in accordance with the PRISMA reporting checklist (available at <http://dx.doi.org/10.21037/apm-21-1167>).

## Methods

### Search strategy

We systematically searched for relevant clinical controlled trials until March 2020 in Cochrane databases, PubMed, Embase, CINAHL, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chongqing VIP, and Wanfang Data. The Chinese keywords included heart valve, aortic valve insufficiency, aortic stenosis, mitral valve atresia, mitral valve stenosis, tricuspid stenosis, surgery, cardiovascular surgery, replacement, continuous nursing, continuity of care, extended care, and discharge plan. English keywords

comprised a combination of subject terms with a wide range of free-text terms, which included cardiac valve/heart valve disease, surgery/operation/replacement/heart surgical procedure, and continuation of care/continuity of care/extended care/discharge plan. Boolean operators were used during searching.

### Inclusion and exclusion criteria

#### Inclusion criteria

##### Study types

Randomized controlled trials, in English or Chinese, were enrolled, regardless of whether the study mentioned concealed allocation or blinding.

##### Subjects

Patients who had been discharged from hospital after HVR were enrolled.

##### Interventions

The control group received conventional treatment and nursing, which included instructions at admission, routine preparation, and health education before and after the surgery, and routine instructions upon discharge. The CC group received CC in addition to the routine treatment and nursing. The main content of CC included the following: (I) health education focusing on disease-related knowledge during hospitalization; (II) a detailed nursing plan after discharge; (III) rehabilitation instructions; and (IV) telephone visits, home visits, or internet-based visits (e.g., via social media). The duration of the intervention was longer than 1 month.

##### Outcome measures

The outcome measures were the following: (I) anticoagulation therapy adherence: patients' adherence to anticoagulation therapy was evaluated by using a self-made scale based on consulting relevant literature and experts, which clearly included the continuity of medication, drug administration of the appropriate dose at the right time, regular tests for relevant indicators, reasonable diets, and self-monitoring. The instrument used a 4-point Likert scale (strongly agree =4, agree =3, disagree =2, strongly disagree =1), with 20 indicating the highest score possible. A higher score indicates better adherence to anticoagulation therapy, a score of 16 or more is considered good adherence, and a score of 16 or less is considered poor adherence. (II) Incidence of anticoagulation-associated complications and adverse events: The complications and adverse events (e.g., hemorrhage, embolism, and thrombosis) of anticoagulation were observed and recorded in both groups. Hemorrhage

was confirmed by chest X-ray/ultrasound or head computed tomography (CT). Other organic conditions that may cause bleeding were ruled out. Cerebral embolism was confirmed by head CT, and peripheral embolism was confirmed by color Doppler ultrasound. Thrombosis was confirmed by color Doppler echocardiography and other examinations. (III) Awareness about anticoagulation therapy: a questionnaire was designed according to the actual situation, including the importance of anticoagulation therapy, the values of regular tests for prothrombin time (PTT) and international normalized ratio (INR), adverse effects and complications, and lifestyle. The evaluation of awareness was divided into 3 levels: fully aware, partially aware, and not aware. The anticoagulation awareness rate = (fully aware + partially aware)/total number. (IV) Quality of life: the World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF) was used to assess the survival status of patients in both groups 12 months after discharge. The WHOQOL-BREF is a 26-item tool distributed under 5 main domains comprising physical domain, psychological domain, levels of independence, social relationships, and environment. Individual items are rated on a 5-point Likert scale where 1 indicates low, negative perceptions; and 5 indicates high, positive perceptions.

### Exclusion criteria

The exclusion criteria included (I) duplicate publications, (II) incomplete baseline data, (III) incomplete reporting, (IV) poor quality of the literature or studies in which the statistical data could not be translated or applied, and (V) self-controlled trials.

### Screening and quality evaluation of studies published

#### Literature screening and information extraction

The procedure for literature screening and quality evaluation was as follows: (I) duplicated articles were removed using NoteExpress software (version 3.2; Aegean Software Corp.); (II) two researchers independently read the titles and abstracts and manually removed the articles that did not meet the inclusion criteria of the present study; (III) the articles were further screened through a reading of the full text and excluded or included according to the inclusion and exclusion criteria of the given study, with any disagreement being settled by consultation with the supervisor; (IV) Two researchers independently extracted information including first author(s), publication year,

follow-up duration, study method, subject characteristics, interventions, and outcome measures. A formal information extraction form was submitted after an agreement was reached between these two researchers.

### Quality evaluation

The two researchers evaluated the methodological quality of the studies included according to the RCT bias risk assessment tool recommended by the Cochrane systematic review guidelines (8). In the case of disagreement, the two researchers discussed or resolved the issue by consulting a third researcher. The evaluation included the following 7 items: (I) random sequence generation; (II) allocation concealment; (III) performance bias (blinding of participants and personnel); (IV) detection bias (blinding of outcome assessment) (V) attrition bias (incomplete outcome data); (VI) reporting bias (selective reporting); and (VII) other bias. Each item was rated as “low risk of bias,” “unclear risk of bias,” or “high risk of bias.” If all the above criteria were met, the possibility of bias was considered to be low and the quality level was “A”; if only some of the criteria were met, the possibility of bias was considered to be moderate and the quality level was “B”; and if none of the criteria were met, the possibility of bias was considered to be high and the quality level was “C”.

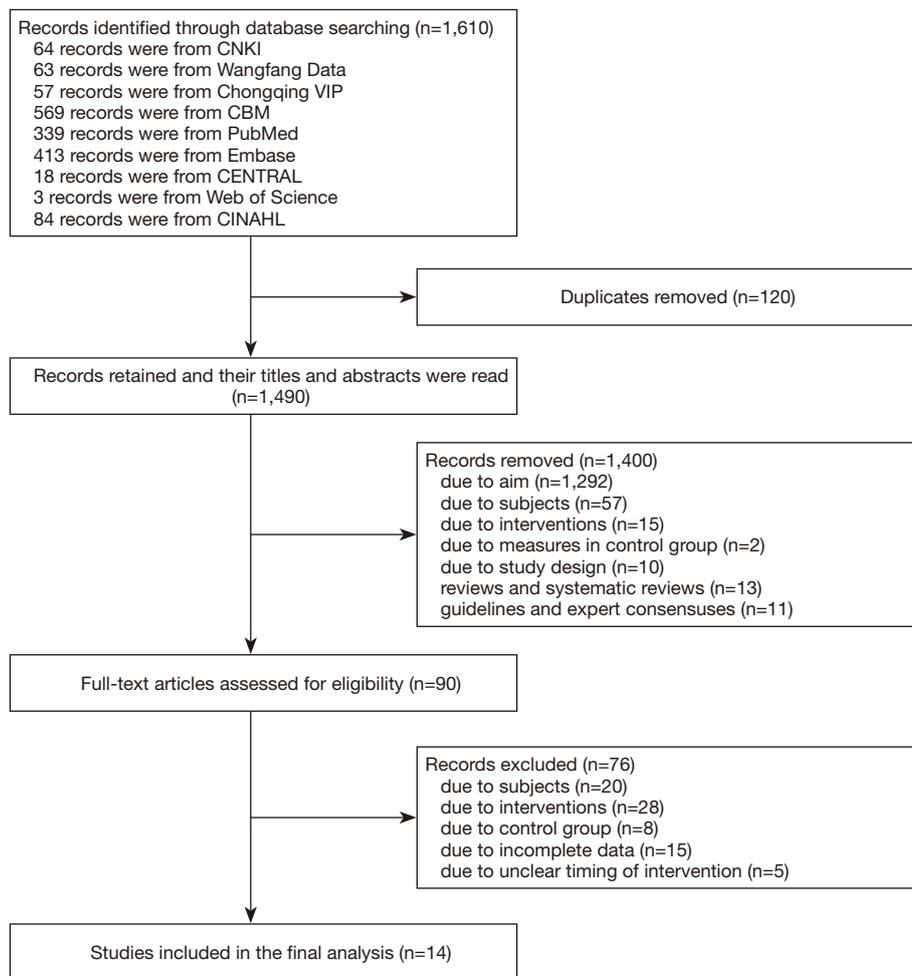
### Statistical analysis

Meta-analysis was performed using the RevMan 5.2 software. Count data are presented with relative risks (RRs), ad measure data are presented with weighted mean differences (WMDs), and all the effect measures are expressed as 95% confidence intervals (CIs). The heterogeneity analysis was performed using the  $\chi^2$  test. When  $I^2 < 50\%$  and  $P \geq 0.1$ , the studies were considered slightly heterogeneous or no-heterogeneous, and a fixed-effects model was used; when  $I^2 \geq 50\%$  and  $P < 0.1$ , possibility of heterogeneity was considered, and a random-effects model was used. A P value of  $< 0.05$  was considered statistically significant.

## Results

### Results of literature retrieval

In total, 1,610 records (753 in Chinese and 857 in English) were retrieved in the initial electronic search. After removal of 120 duplicate articles, 1,400 documents were further



**Figure 1** Flow diagram depicting the process of study selection.

removed according to the inclusion and exclusion criteria after reading the titles and abstracts. Subsequently, the full texts were downloaded and read, and 76 articles that did not meet the inclusion criteria were excluded. Finally, 14 randomized controlled trials (RCTs) (9-22) involving 1,825 patients (920 and 905 patients in each group) entered the final analysis. All were Chinese-language articles. A flowchart depicting the selection process is provided in *Figure 1*.

#### **General characteristics of the included articles**

These 14 Chinese-language articles were published between 2014 and 2019. The general characteristics of these articles

are summarized in *Table 1*.

#### **Quality levels of the included literature**

All 14 articles were grade B (*Table 2*).

#### **Results of the meta-analysis**

##### **Compliance with anticoagulation therapy**

In all, 7 of the included studies used anticoagulation adherence as an outcome measure (9,11,12,16-18,22); among these, 3 reported patients' anticoagulation adherence at 3 months, 6 months, and 1 year postoperatively (9,11,16), 1 reported patients' anticoagulation adherence at 6 months and 1 year postoperatively (12), and 3 reported patients'

**Table 1** General characteristics of the included articles

Included article	Sample size (n): Intervention group/control group	Age (years, $\bar{x}\pm$ SD): Intervention group/control group	Interventions	Interventions offered via	Duration of intervention measures	Outcome
Li B (2014)	61/60	47.28 $\pm$ 8.62/45.92 $\pm$ 8.36	Establishing a disease-specific follow-up register; Establishing a disease-specific follow-up team composed of medical professionals; Maintaining a "postoperative self-monitoring record"	Telephone calls	12 months	(I)
Liao JL (2015)	60/60	42.7 $\pm$ 2.6	Establishing a disease-specific follow-up team composed of medical professionals; Establishing follow-up cases	Telephone calls	6 months	(II)
Lu M (2015)	40/40	43.2 $\pm$ 10.9/48.2 $\pm$ 11.5	Establishing individual patient's care files; Establishing a transitional care team	Telephone calls + home visits	12 months	(I), (II)
Wu HL (2015)	23/23	43.42 $\pm$ 9.32/44.05 $\pm$ 9.45	Establishing individual patient's care files	Telephone calls + home visits	12 months	(I), (II)
Yuan YR (2015)	60/60	48.5 $\pm$ 10.5	Establishing a follow-up team composed of medical professionals; Establishing follow-up records	Telephone calls	6 months	(II)
Xu BL (2016)	130/138	47.52 $\pm$ 1.52/51.00 $\pm$ 1.63	Establishing individual patient's files	Telephone calls + outpatient visits	12 months	(II), (IV)
Hu HH (2016)	50/50	44.50 $\pm$ 8.33/45.00 $\pm$ 10.50	Establishing a disease-specific follow-up team composed of medical professionals; Establishing a disease-specific follow-up register	Telephone calls	6 months	(II)
Zhou N (2016)	200/178	43.3 $\pm$ 5.7/43.4 $\pm$ 5.8	Establishing a disease-specific follow-up team composed of medical professionals; Maintaining a postoperative self-monitoring record	Telephone calls	12 months	(I), (II), (III)
Yang QL (2017)	43/43	49.1 $\pm$ 7.7/49.3 $\pm$ 7.9	Establishing individual patient's records; Conducting visits by dedicated nursing staff	Telephone calls	36 months	(IV)
Xu DN (2017)	40/40	49.5 $\pm$ 8.1/48.7 $\pm$ 7.8	Conducting visits by dedicated nursing staff	Telephone calls	12 months	(I), (II), (IV)
Wang J (2017)	48/48	47.25 $\pm$ 7.12/47.72 $\pm$ 7.34	Conducting visits by dedicated nursing staff	Telephone calls	12 months	(I)(IV)
Baoli J (2017)	45/45	45.3 $\pm$ 6.7/45.1 $\pm$ 6.9	Maintaining a follow-up record; Establishing a disease- specific follow-up team composed of medical professionals	Telephone calls	12 months	(I), (II)
Hou F (2017)	65/65	58.91 $\pm$ 8.23/58.80 $\pm$ 9.04	Establishing a disease-specific follow-up team composed of medical professionals; Establishing electronic information files	Telephone calls + outpatient visits	12 months	(II)
Chen PP (2019)	55/55	47.58 $\pm$ 11.78/48.03 $\pm$ 11.63	Establishing a continuity of care intervention team; Establishing continuity of care records for patients	Telephone calls + home visits	12 months	(II)

Outcome measures: (I) anticoagulation therapy adherence, (II) incidence of anticoagulation-associated complications and adverse events, (III) anticoagulant awareness, (IV) quality of life.

Table 2 Quality levels of included articles

Articles included	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding Of outcome assessment	Incomplete outcome data	Selective reporting	Other biases	Quality level
Li B (2014)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Liao JL (2015)	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Lu M (2015)	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Wu HL (2015)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Yuan YR (2015)	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Xu BL (2016)	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Hu HH (2016)	High risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Zhou N (2016)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Baoli J (2017)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Xu DN (2017)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Wang J (2017)	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Yang QL (2017)	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Hou F (2017)	Low risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B
Chen PP (2019)	Unclear risk of bias	Unclear risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	Low risk of bias	B

B, as a quality grade, considered to be moderate

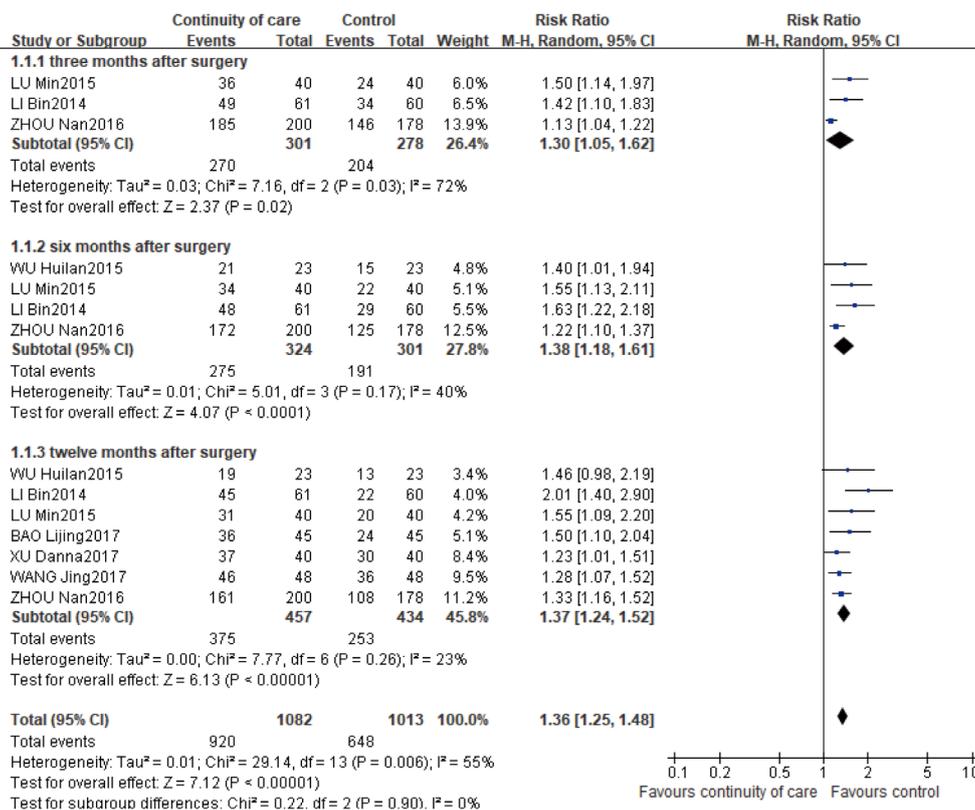


Figure 2 Forest plot for the impact of the continuity of care on anticoagulation therapy adherence.

anticoagulation adherence at 1 year postoperatively (17,18,22). The results of the  $\chi^2$  test showed considerable heterogeneity among the included studies ( $I^2 > 50\%$ ) and no statistical homogeneity ( $P > 0.05$ ); therefore, a random-effects model was applied, which showed that the CC group had significantly better anticoagulation adherence than did the control group [RR = 1.36, 95% CI: (1.25, 1.48),  $P < 0.00001$ ; Figure 2].

**Anticoagulant awareness**

In all, 3 of the included studies used anticoagulant awareness as an outcome measure (10,11,16); of these, 2 reported patients’ anticoagulant awareness at 3 months, 6 months, and 1 year postoperatively (11,16), and one reported patients’ anticoagulant awareness at 6 months postoperatively (10). The results of the  $\chi^2$  test showed that there was no statistical heterogeneity among the included studies ( $P = 0.74$ ,  $I^2 = 0\%$ ), and therefore a fixed-effects model was applied, which showed that the CC group had significantly higher anticoagulant awareness than the control group [RR = 1.14, 95% CI: (1.09, 1.18),  $P < 0.00001$ ; Figure 3].

**Incidence of anticoagulation-associated complications and adverse event**

In all, 9 of the included literature used the incidence of complications and adverse events associated with anticoagulation as an outcome measure; of these, 1 reported anticoagulation-associated complications and adverse events at 6 months and 1 year after discharge (12), 2 reported anticoagulation-associated complications and adverse events at 6 months after discharge (13,15), and 6 reported anticoagulation-associated complications and adverse events at 1 year after discharge (14,16,17,20-22). The results of the  $\chi^2$  test showed that there was no statistical heterogeneity among the included studies ( $P = 0.79$ ,  $I^2 = 0\%$ ), and therefore a fixed-effects model was applied, which showed that the CC group had significantly lower incidence of anticoagulation-associated complications and adverse events than did the control group [RR = 0.24, 95% CI: (0.17, 0.35),  $P < 0.00001$ ; Figure 4].

**Quality of life**

In all, 4 articles (14,17-19) used the quality of life (in

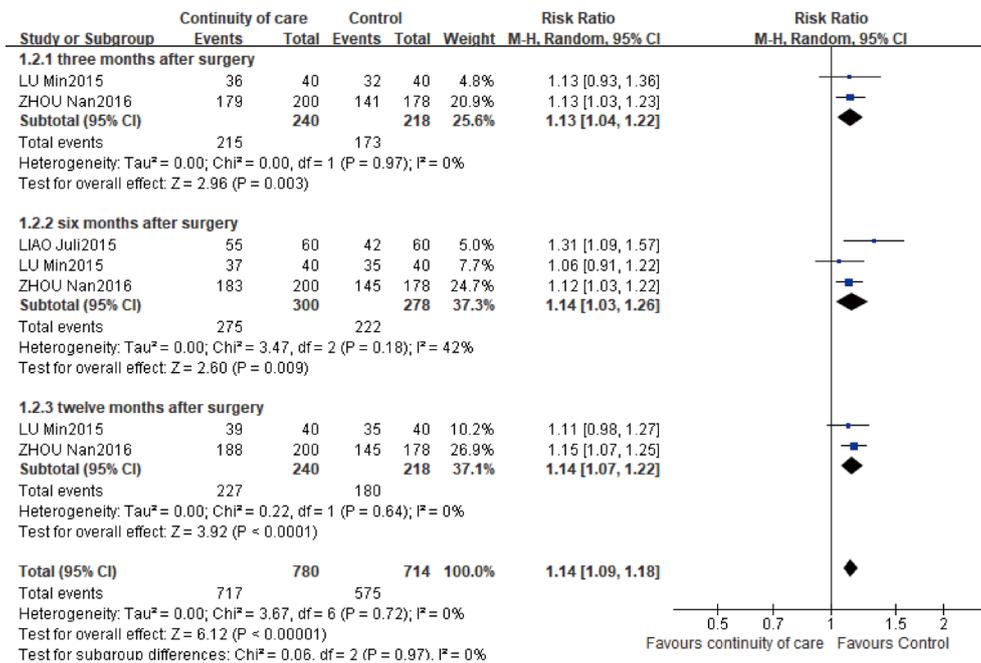


Figure 3 Forest plot for the impact of the continuity of care on anticoagulant awareness.

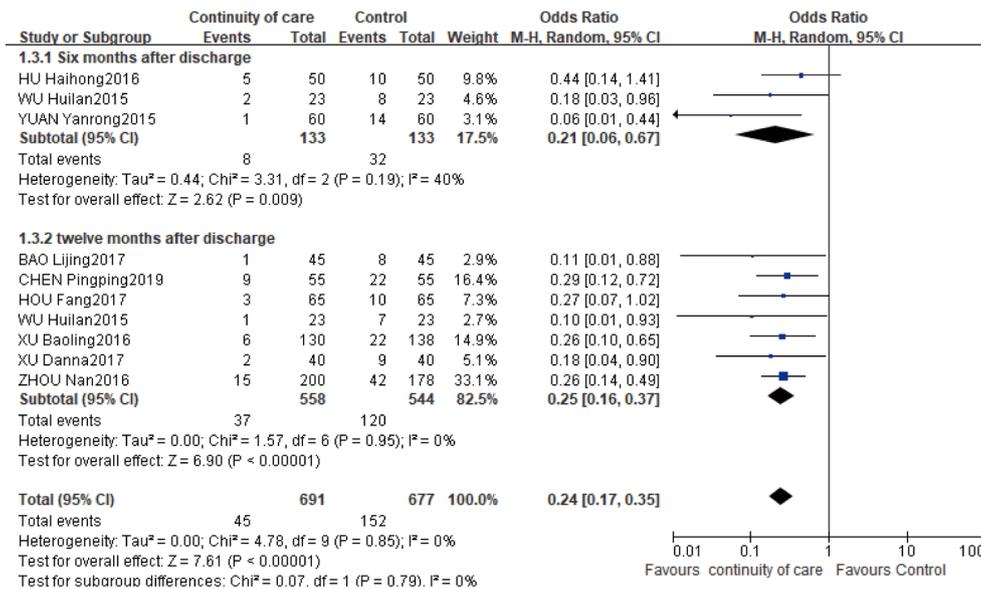


Figure 4 Forest plot for the impact of the continuity of care on the incidence of anticoagulation-associated complications and adverse events.

terms of physical domain, psychological domain, levels of independence, social relationships, and environment) as an outcome measure. The results of the  $\chi^2$  test showed considerable heterogeneity among the included studies

(I<sup>2</sup>>50%) and no statistical homogeneity (P>0.05); therefore, a random-effects model was applied, which showed that these 5 domains reflecting quality of life had significant differences between the two groups: physical domain [MD

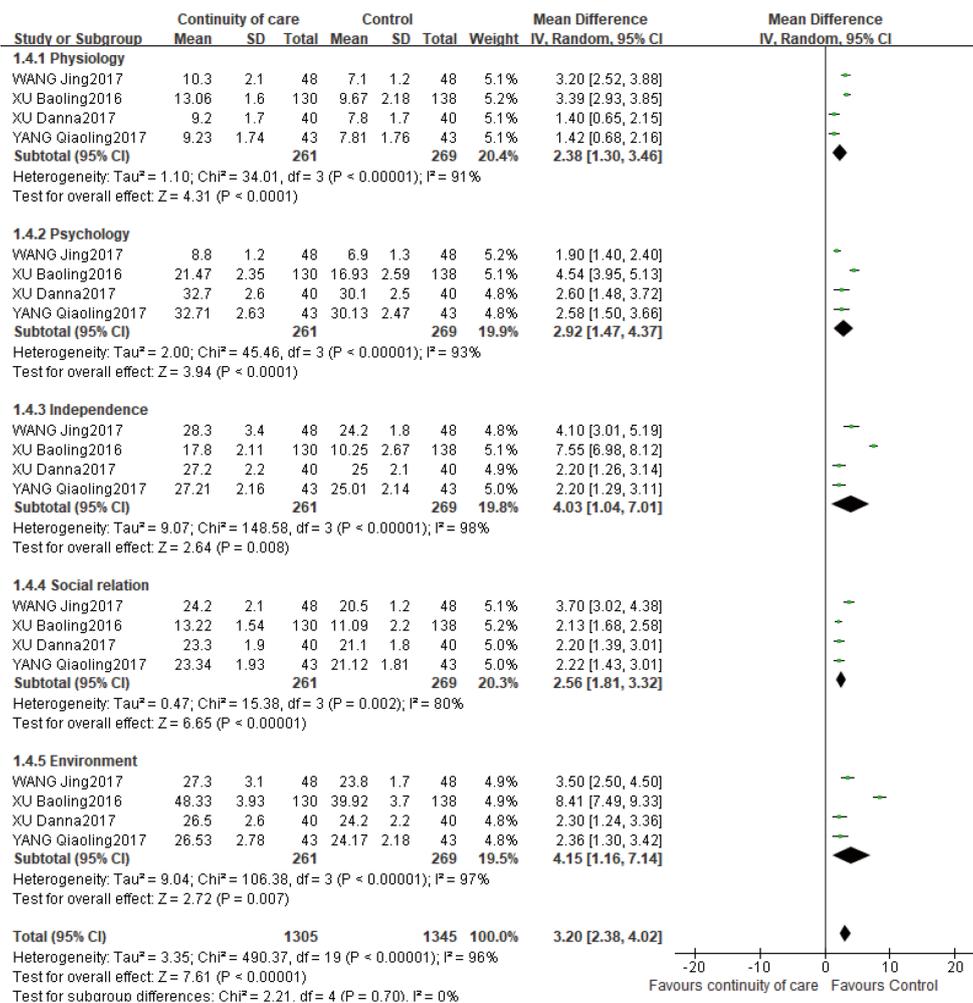


Figure 5 Forest plot for the impact of the continuity of care on quality of life.

=2.38, 95% CI: (1.30, 3.46), P<0.0001], psychological domain [MD =2.92, 95% CI: (1.47, 4.37), P<0.0001], levels of independence [MD =4.03, 95% CI: (1.04, 7.01), P=0.008], social relationships [MD =2.56, 95% CI: (1.81, 3.32), P<0.00001], and environment [MD =4.15, 95% CI: (1.16, 7.14), P=0.007]. Obviously, patients in the CC group had significantly higher quality of life than did those in the control group (Figure 5).

**Discussion**

*Methodological quality of the included literature*

This meta-analysis was performed to investigate the effect of CC on anticoagulation therapy and quality of life after

HVR. A total of 14 articles were included, all of which had a quality level of B. Overall, 5 articles described the randomization method and process, 5 did not elaborate on the grouping method, and 3 grouped the subjects in a nonrandomized manner (such as by time of admission or by the odd or even numbers of the admission numbers). Furthermore, 14 articles did not mention allocation concealment, and the risk of bias was evaluated as low because it was difficult to apply the blind method in discharged patients and the outcome indicators were not affected by the blind method. All 14 articles offered complete follow-up data, and there was no dropout of participants or withdrawal during the follow-up. The baseline data including gender and age were matched between the CC group and the control group.

### *Effectiveness of CC*

- (I) Impact of CC on anticoagulation therapy adherence, anticoagulant awareness, and incidence of anticoagulation-associated complications and adverse events: As seen in the 14 included RCTs, CC helped to improve anticoagulation therapy adherence and anticoagulant awareness while lowering the incidence of anticoagulation-associated complications and adverse events. Bleeding and embolism due to inappropriate anticoagulation therapy is the most common life-threatening complication after HVR (23,24). Due to the lack of knowledge and awareness concerning the disease, patients often cannot properly manage their disease or adjust their lifestyles, and their compliance with treatment protocols decreases with time after discharge, leading to the occurrence of anticoagulation-associated complications (9). Our meta-analysis showed that CC improved patients' compliance with anticoagulation therapy and raised their awareness of anticoagulants at 3 months, 6 months, and 1 year after discharge, and the compliance and awareness did not decrease with time after discharge; in addition, CC effectively reduced the incidence of anticoagulation-associated complications and adverse events at 6 months and 1 year after discharge.
- (II) Impact of CC on quality of life: compared with the routine nursing practice, CC effectively improved the postoperative quality of life. However, the forest plot showed heterogeneity in all 5 domains (physical domain, psychological domain, levels of independence, social relationships, and environment) reflecting quality of life, which may be explained by the different severities of disease among participants in different studies or by the inconsistent CC interventions, intervention duration, and/or monitoring time points. Although the specific interventions of CC varied, they might include establishing a follow-up team of healthcare professionals, establishing and maintaining personal health record, offering health education on disease-related knowledge during hospitalization, developing discharge plans, and conducting post-discharge follow-up involving home visits and phone calls. It has been proposed that the quality of life after surgery is a dynamic process that will change with time and environment (25). As patients gradually recover from

a surgery, their ability to take care of themselves increases, their confidence starts to be restored, and the quality of life gradually improves, which can reach a satisfactory level by 6 months after surgery (7). However, a survey outside of China revealed that patients were prone to fatigue and had low work and life abilities at 6 months after surgery, and most patients' mobility only recovered to about 55% of the normal range in the same age groups. The impact of CC on quality of life at different time points after interventions should be further investigated.

### *Limitations*

The specific interventions and the content of health education were not completely consistent among different studies, which had an influence on the outcomes. There were no objective outcome indicators (such as blood pressure, blood lipids, or blood glucose) in this analysis. Despite the rapid development of CC in China in recent years, there were still many differences in nursing intervention measures compared with the relatively mature nursing intervention modes in foreign countries. Therefore, only Chinese-language articles were included in this analysis, and we did not perform a search for gray literature, which might have led to clinical heterogeneity.

### **Conclusions**

CC can effectively improve patients' compliance with anticoagulation therapy and raise their awareness about medications, reduce the incidences of complications and adverse events, and thus improve the patients' quality of life. However, only a limited number of high-quality RCTs were included in our current analysis, and there are certain heterogeneities in the specific interventions, content of health education, and duration of intervention. Studies with more rigorous designs are warranted to further validate the impacts of CC on anticoagulation therapy adherence and quality of life after HVR.

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## Footnote

*Reporting Checklist:* The authors have completed the PRISMA reporting checklist. Available at <http://dx.doi.org/10.21037/apm-21-1167>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/apm-21-1167>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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