



IMPROVING HEALTH FOR BETTER FUTURE LIFE: STRENGTHENING FROM BASIC SCIENCE TO CLINICAL RESEARCH

Edited by
Muthmainah, Hanik Badriyah Hidayati and Budi Yanti

IMPROVING HEALTH FOR BETTER FUTURE LIFE: STRENGTHENING FROM BASIC SCIENCE TO CLINICAL RESEARCH

The proceedings of the 3rd International Conference on Health, Technology, and Life Science (ICO-HELICS 2022) shared ideas, pre-clinical and clinical research results, and literature review, on various aspects of medical science including heart disease, stroke, cancers, vaccines, infections, immunological disease, reproductive health, pharmacology and other health diseases. The proceedings aim to deliver new insights to the knowledge and practice of health workers and equip them in providing the best quality health care and clinical outcomes.

As the idea of advanced clinical research originated from basic or fundamental research, it explores the life processes that are universal in their application to scientific knowledge. Therefore, these proceedings will also be of interest to academics, practitioners, health workers, and professionals involved in medical research.



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Improving Health for Better Future Life: Strengthening from Basic Science to Clinical Research

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Preface

Many areas in health and medical research have been consistently successful in providing the best quality health care and best clinical outcomes. Astonishing enhancement of heart disease, stroke, cancers, vaccines, infections, immunological disease, and other health diseases is evidence of the power of science to save and improve lives. Medical researchers who work in clinical research have studied health and illness in people, which also proves and protects public health. Furthermore, the idea of advanced clinical research originated from basic research or fundamental research, the study of life processes that are universal in their application to scientific knowledge. Clinical Research addresses important questions of normal function and disease using human subjects. The researchers need to expand their capabilities by adding up the medical updates through journals, scientific discussions, and conferences.

To strengthen the clinical research, a scientific conference need to add to the annual agenda. Therefore, the Medical Faculty of Universitas Sebelas Maret Indonesia which is among the top medical faculty in Indonesia would like to present the **Third International Conference on Health, Technology, and Life Science (ICO-HELICS)**.

ICO-HELIC 2022 is held fully online and enhance with virtual reality experience to provide all participants with interactive learning experiences in this International Conference on Health, Technology, and Life Science.

Dr. Revi Gama Hatta Novika, SST.,M.Kes



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*Medical (basic science, clinical, translational research,
medical education, and miscellaneous)*



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A cost-effectiveness analysis of ferric carboxymaltose in patients with heart failure and iron deficiency: A systematic review

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ABSTRACT: Iron deficiency is one of the heart failure comorbidities. This study aims to evaluate and conclude the cost-effectiveness of ferric carboxymaltose in heart failure patients with iron deficiency. This was a systematic review of all articles collected from PubMed, Scopus, Web of Science, EBSCO, ProQuest, Science Direct, and Global Health Databases, published from 2012 to 2022. Seven studies from 679 articles were included. One article used the Markov model study design, five articles used a model-based study, and one article used a cost-utility approach. South Korea has the highest ICERs at \$18,254/QALY. Ferric carboxymaltose is cost-effective for heart failure with iron deficiency, with an average ICER value of \$7,814/QALY and a median value of \$6,678/QALY.

1 INTRODUCTION

Heart failure still a major health problem with a global prevalence of 64.3 million patients (Roger 2021). These can cause higher re-hospitalization, hospitalization duration, and economic burden (Virani *et al.* 2020). A high rate of heart failure cases led to high estimated medical costs, with an expense of 31 billion USD in 2012 and predicted to increase the cost by about 127% in 2030 (Mozaffarian *et al.* 2016).

European Society of Cardiology admits iron deficiency as a heart failure comorbidity relates to reducing activity capacity, increasing hospitalization risks, worsening the Health-Related Quality of Life (HRQoL), and death (Martens *et al.* 2018; McMurray *et al.* 2012). Those have been reported at 50% in chronic heart failure and 80% in acute heart failure patients (Cohen-Solal *et al.* 2014). Until 2021, some studies have proved the efficacy and safety of ferric carboxymaltose intravenous, which can improve the clinical condition, increase HRQoL, decrease hospitalization rate, and reduce the duration of hospitalization (McEwan *et al.* 2021; van Veldhuisen *et al.* 2017).

According to the condition above, several studies raised from clinical studies to economic studies, such as cost-effectiveness analysis (CEA), to support the stakeholders in each country to evaluate the economic impact and the effectiveness of ferric carboxymaltose in patients with heart failure and iron deficiency (Hofmarcher & Borg 2015; van Veldhuisen *et al.* 2017). Those studies report varied results and need to be systematically reviewed about studies' evidence related to ferric carboxymaltose cost-effectiveness and bring a systematic scientific conclusion (Page *et al.* 2021).

2 METHODS

2.1 Study design

This was a systematic review using the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) protocol (Page *et al.* 2021).

2.2 Searching strategy

We obtained the articles using an electronic database, namely PubMed (MEDLINE), Scopus, Publons, Science Direct, EBSCO, ProQuest, and Global Health databases. We used varied keywords, including “cost-effectiveness”, “ferric carboxymaltose”, “heart failure”, and “iron deficiency” and continued with the Boolean operation strategy.

We applied articles from 2012 to 2022 because FCM was a relatively new therapy regimen for heart failure. The first efficacy of FCM in heart failure was the 2007 FAIR-HF (Anker *et al.* 2009). It grew until 2012 in ESC guidelines for heart failure patients with iron deficiency (McMurray *et al.* 2012). Ultimately, cost-effectiveness research of the FCM began to emerge in the last ten years worldwide.

2.3 Article criteria

The article inclusion criteria used were (i) relevant economic evaluation studies, (ii) patients aged >18 years old who were diagnosed with symptomatic heart failure HFrEF or NYHA class II-IV with iron deficiency, (iii) included ICER and QALY outcomes, (iv) English journal, (v) published from 2012–2022, (vi) evaluated ferric carboxymaltose cost-effectiveness, (vii) using ferric carboxymaltose as therapy, (viii) full-text accessed.

Articles would be excluded if (i) review article or protocol or an abstract, (ii) the population was heart failure patients without iron deficiency or heart failure patients with iron deficiency but received iron supplementation except for ferric carboxymaltose, (iii) patients with comorbidities such as chronic kidney disease and cancer.

2.4 Study selection

The results from article searching would be inserted into the Mendeley desktop with each database folder; then the summary would be put into Microsoft Excel. Afterward, these results would be screened by QFS and NPI independently according to the title and abstract. We would discuss if there were different results and would be deliberated with the RPF if the discussion ended without a deal.

2.5 Extraction and data synthesis

All extractions were made by QFS and NPI independently according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Quality Assessment 2013 (Kemmak *et al.* 2021). The mark ‘Y’ got a score of 1, ‘P’ scored 0.5, and ‘N’ scored 0. All results were classified into high quality (>85%), excellent quality (<70–85%), good quality (<55–70%), and low quality (<55%). All variations of extraction results and critical appraisal were discussed with RPF and YAM. The evaluated articles were extracted in the results table. Data synthesis was conducted using a narrative descriptive method because the study results varied among countries (Franklin & Thorn 2019; Rashki Kemmak *et al.* 2022).

3 RESULTS

We found 679 articles. After we excluded 204 duplicated articles, 178 review articles, abstracts, or protocols, 207 articles that did not relate to ferric carboxymaltose, 63 articles that did not include iron deficiency, and 20 articles that did not meet the inclusion and exclusion criteria, we ended up with 7 full-text eligible articles (Figure 1).

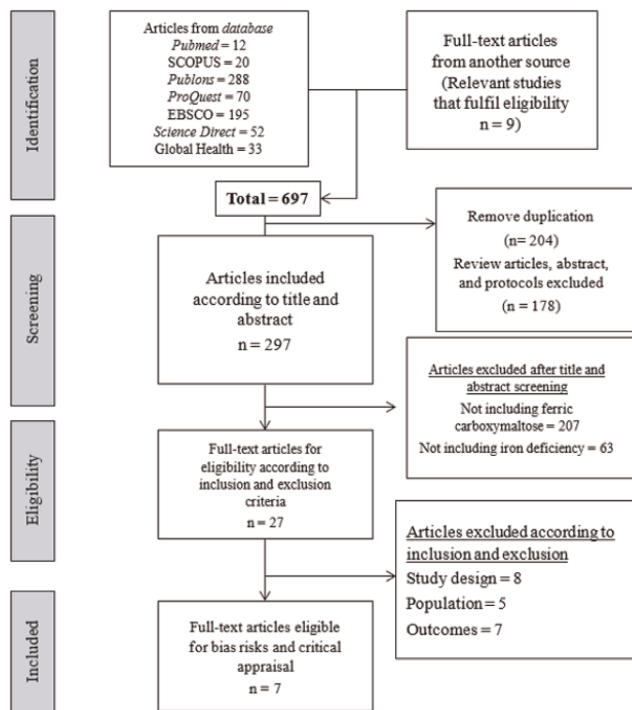


Figure 1. Flowchart of systematic review according to PRISMA.

Table 1 explains the summary of seven selected studies in this systematic review. The patients were HFrEF with iron deficiency. Ferric carboxymaltose as the choice of therapy was the primary intervention in this article. The main output to be valued was ICER and QALY. Meanwhile, Table 2 was the summary of critical appraisal using the CHEERS Checklist 2013.

Table 1. The summary of selected studies.

Author, year	Currency/ year	Threshold	Health Outcomes (QALY)	Incremental QALY*	Incremental Costs	ICER
(Comin-Colet <i>et al.</i> 2015)	€/2013	€30.000	0.335	0.037	€824,17/€597,59	€6,123/ QALY
(Gutzwiler <i>et al.</i> 2012)	€ and £ / spain 2009	€22.200– €33.300 (£20.000– 30.000)	0.336	0.038	€852(£768)/€687 (£619)	€4,414 (£3,977)/ QALY
(Hofmarcher & Borg 2015)	SEK and €/2014	SEK 500.000 (€54.300)	0.036	0.038	SEK 8,602 (€935)/ SEK 8,512 (€632)	SEK 75,389 (€8,194)/ QALY
(Hofmarcher <i>et al.</i> 2018)	€/2017	€45.000	N/A	0.050	Denmark (€1,082) Finlandia (€961) Norwegian (€1,275) Sweden (€1,068)	€6,500– €9,000/ QALY
(Lim <i>et al.</i> 2014)	\$/2012	N/A	N/A	0.021	Incremental cost \$466	\$22,192 (₩25,01 0.451)/ QALY

(continued)

Table 1. Continued

Author, year	Currency/ year	Threshold	Health Outcomes (QALY)	Incremental QALY*	Incremental Costs	ICER
(Rognoni & Gerzeli 2019)	€/2018	€20.000	0.703	0.061	€3,296/€3,699	€4,414/ QALY
(McEwan <i>et al.</i> 2021)	GBP (£), USD (\$), EUR (€), CHF (Fr.) /2020	UK: £20.000; USA: \$100.000; Switzerland: Fr.50.000; Italy: €30.000	UK 0.430; Italy 0.430; Switzerland 0.440; USA 0.440	N/A	UK £10,700/£10,839 Italia €26,489/ €25,939 Swiss Fr45,028/Fr47,733 USA \$67,475/ \$70,896	UK domi- nant, Italia €1,269/ QALY, Swiss dominant, USA dominant

*QALY, *Quality Adjusted Life Years*; FCM, *Ferric Carboxymaltose*; ICER, *Incremental Cost Effectiveness Ratio*; ESC, *European Society of Cardiology*; SEK, *Sweden Krona*; UK, *United Kingdom*; USA, *United States of America*; USD, *United States Dollar*; EUR, *Euro*; CHF, *Switzerland Franc*; GBP, *British pound sterling*; N/A, *Not Applicable*; €, *Euro*; £, *Pound*; \$, *Dollar*; Fr., *Franc*.

Table 2. Analysis results of bias risks using CHEERS 2013.

Item no	Checklist	Comin- Colet <i>et al.</i>	Gutz- willer <i>et al.</i>	Hofmar- cher and Borg	Hof- marcher <i>et al.</i>	Lim <i>et al.</i>	Rognoni and Gerzeli	McEwan <i>et al.</i>
1	Title	Y*	P*	Y	P	Y	Y	Y
2	Abstract	P	P	P	P	Y	P	Y
3	Background and objec- tives	Y	Y	Y	Y	Y	Y	Y
4	Target population and subgroups	P	P	P	P	Y	P	Y
5	Setting and location	P	Y	Y	Y	P	Y	Y
6	Study perspective	Y	Y	Y	P	Y	Y	Y
7	Comparators	Y	Y	Y	Y	Y	P	Y
8	<i>Time horizon</i>	Y	Y	Y	Y	Y	Y	Y
9	<i>Discount rate</i>	Y	Y	Y	Y	N*	Y	Y
10	Choice of health outcomes	Y	Y	Y	Y	Y	Y	Y
11a	Measurement of Effec- tiveness (<i>single study- based</i>)	Y	Y	Y	Y	Y	N/A*	Y
11b	Measurement of effective- ness (<i>model-based</i>)	N/A	N/A	N/A	N/A	N/A	Y	N/A
12	Measurement and evalua- tion of preference based outcomes	N	Y	Y	Y	Y	Y	Y
13a	Estimating resources and costs (<i>single study-based</i>)	Y	Y	Y	Y	Y	N/A	Y
13b	Estimating resources and costs (<i>model-based</i>)	N/A	N/A	N/A	N/A	N/A	Y	N/A
14	Currency, price date, and conversion	P	Y	Y	Y	Y	P	Y

(continued)

Table 2. Continued

Item no	Checklist	Comin-Colet <i>et al.</i>	Gutzwiller <i>et al.</i>	Hofmarcher and Borg	Hofmarcher <i>et al.</i>	Lim <i>et al.</i>	Rognoni and Gerzeli	McEwan <i>et al.</i>
15	Choice of model	Y	Y	P	P	Y	Y	Y
16	Assumptions	Y	Y	Y	Y	Y	Y	N
17	Analytical methods	Y	Y	Y	Y	P	Y	Y
18	Study parameters	Y	Y	Y	Y	Y	Y	Y
19	Incremental costs and outcomes	Y	Y	Y	Y	Y	Y	Y
20a	Characterizing uncertainty (<i>single study-based</i>)	P	P	P	N	N	N/A	P
20b	Characterizing uncertainty (<i>model-based</i>)	N/A	N/A	N/A	N/A	N/A	Y	N/A
21	Characterizing heterogeneity	N	P	P	P	Y	N	Y
22	Study findings, limitations, generalizability, and current knowledge	Y	Y	Y	Y	Y	Y	Y
23	Source of funding	Y	Y	Y	Y	Y	Y	Y
24	Conflicts of interest	Y	Y	Y	Y	Y	Y	Y
	Quality of Article	Very Good	High	High	Very Good	High	High	High

*Y, Yes; N, No; P, Partially; N/A, Not Applicable

4 DISCUSSION

4.1 The threshold and ICER of every country in the selected study

This systematic review compared the cost-effectiveness by considering the economic threshold. Therefore, ICER was changed into USD/\$ (according to Purchasing Power Parity over Gross Domestic Product or GDP in 2022). The Rognoni dan Gerzeli' study from Italy showed a close difference between the threshold and ICER, with only \$17,001 (\$4,815/QALY for ICER and \$21,816 for the threshold) (Rognoni & Gerzeli 2019). Moreover, Hofmarcher dan Borg' study from Sweden had the highest difference between the threshold and ICER (\$8,938/QALY for ICER and \$59,230 for the threshold), which showed the possibility of using ferric carboxymaltose as therapy was highly cost-effective (Hofmarcher & Borg 2015).

4.2 The uncertainty analysis from selected studies

The results from seven studies showed a good situation equally to Deterministic Sensitivity Analysis (DSA), Univariate Sensitivity Analysis (USA), or Probabilistic Sensitivity Analysis (PSA), which were applied in economic evaluation. The average results in studies with PSA were in the upper right quadrant, which meant that the cost and effectiveness were higher. The differences in QALY, cost or ICER showed that FCM was cost-effective. Therefore, even though the cost was higher, FCM could increase the quality of life and apply to those countries.

4.3 The cost of ferric carboxymaltose therapy

The difference between Gross National Income (GNI) per capita and the health care system was not so obvious, whereas the GNI per capita in high-income countries (HIC), according

to the World Bank (2022), is >\$12,695. That's why the intervention cost and threshold of those countries were equally higher in FCM than in placebo.

FCM cost had various interpretations, with studies from North Europe countries, Norway, and Sweden, showing that FCM cost could cut the total treatment cost compared with a placebo. The FCM cost was the same high as the placebo in Denmark, but higher than the placebo in Finland (Hofmarcher *et al.* 2018). However, the effectiveness and the advantage to the patient's condition were higher with FCM therapy than with the placebo one, thus, we could say that FCM therapy was cost-effective.

On the other hand, the discount rate of FCM was not valid for six studies because of the short time horizon, which was 24–52 weeks. It's only the study by McEwan *et al.* that applied a discount rate with an amount of 3,5% for the UK and 3% for Switzerland, Italy, and the USA (McEwan *et al.* 2021). The age of the population used in seven studies (>60 years old, who were not productive in the majority) showed that the indirect medical cost of FCM therapy did not significantly affect the study results of FCM cost-effectiveness.

4.4 *The clinical outcomes of ferric carboxymaltose in QALY*

The average incremental QALY of FCM compared with the placebo was 0.041 QALY, which showed an increase in the patient's quality of life toward complete health. The highest clinical outcome was the study in Italy which showed a value of QALY 0.703 for FCM, with an incremental QALY amount of 0.061 QALY (Rognoni & Gerzeli 2019). This value was near to score of 1, which meant complete health. Also, the healthcare system in Italy was excellent and had a high focus on heart failure treatment and patient compliance with therapy. The Markov study model was used to present the cost and outcomes together. This study also used the approach by Delphi to ask the clinicians about the clinical progress of the patients via e-survey (van Veldhuisen *et al.* 2017).

Furthermore, the lowest clinical outcome was in Spain with 0.335 QALY in FCM, with the incremental QALY being 0.037 QALY (Comin-Colet *et al.* 2015). South Korea had the lowest incremental QALY FCM compared with the placebo, with 0.021 QALY. This number could not be used to value the progress of patients' healthy functioning, as there was no data about QALY FCM after the incremental (Lim *et al.* 2014). However, it still indicated the quality-of-life improvement with FCM therapy. In all studies that presented the QALY index, ferric carboxymaltose was more cost-effective.

4.5 *Limitations of systematic review*

This systematic review could not make a comprehensive conclusion due to study heterogeneity and time horizon. The discount rate was not able to perform for these six studies, and using the CHEERS checklist to measure the study's quality was subjective.

5 CONCLUSIONS

The cost-effectiveness of ferric carboxymaltose for therapy in heart failure patients with iron deficiency is higher than placebo or without therapy, with the lowest FCM ICER value in seven studies being \$1,384/QALY in Italy and the highest in South Korea. The average ICER is \$7,814/QALY, with a median value of \$6,678/QALY.

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