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Cost-Effectiveness Analysis of Open Versus Endovascular Revascularization for Chronic Mesenteric Ischemia

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Cost-Effectiveness Analysis of Open Versus Endovascular Revascularization for Chronic Mesenteric Ischemia

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Background: Recent studies have shown a trend supporting endovascular revascularization (ER) in the treatment of chronic mesenteric ischemia (CMI). However, few studies have compared the cost effectiveness of ER and open revascularization (OR) for this indication. The purpose of this study is to conduct a cost-effectiveness analysis comparing open versus ER for CMI.

Methods: We built a Markov model with Monte Carlo microsimulation using transition probabilities and utilities from existing literature for CMI patients undergoing OR versus ER. Costs were derived from the hospital perspective using the 2020 Medicare Physician Fee Schedule. The model randomized 20,000 patients to either OR or ER and allowed for 1 subsequent reintervention with 3 other intervening health states: alive, alive with complications, and dead. Quality-adjusted life years (QALYs), costs, and incremental cost-effectiveness ratio (ICER) were analyzed over a 5-year period. One-way sensitivity and probabilistic sensitivity analyses were conducted to study the impact of parameter variability on cost effectiveness.

Results: OR cost $4,532 for 1.03 QALYs while ER cost $5,092 for 1.21 QALYs, leading to an ICER of $3,037 per QALY gained in the ER arm. This ICER was less than our willingness to pay threshold of $100,000. Sensitivity analysis demonstrated that our model was most sensitive to costs, mortality, and patency rates after OR and ER. Probabilistic sensitivity analysis demonstrated ER would be considered cost effective 99% of iterations.

Conclusions: This study found that while 5-year costs for ER were greater than OR, ER afforded greater QALYs than OR. Although ER is associated with lower long-term patency and higher rates of reintervention, it appears to be more cost effective than OR for the treatment of CMI.

INTRODUCTION

Chronic mesenteric ischemia (CMI) is caused by significant atherosclerotic mesenteric vessel stenosis with an incidence of around 6–29%.[1,2] This however, could be higher in older populations.[1,2] Although symptoms do not emerge unless at least 2 of the mesenteric arteries are affected in most patients, untreated CMI can progress to a fatal episode of acute mesenteric ischemia. The 5-year mortality rate for untreated individuals has been reported to be between 40% if asymptomatic and 100% if symptomatic.[3]

CMI can be a particularly debilitating disease; therefore, apart from treating underlying pathology, a major goal for the treatment of CMI is to improve

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the quality of life for patients. Blauw et al. used the EuroQol-5D (EQ-5D) survey questionnaire to assess patients before and after CMI revascularization with either open techniques or endotechniques and found that revascularization was linked to an overall increase in quality of life, as well as improvements in activity, pain, and discomfort.[4]

Revascularization is the mainstay treatment as medical management carries high risk of deterioration. Since the first mesenteric endarterectomy performed by Shaw in 1958, the treatment modalities and disease understanding for mesenteric ischemia has come a long way.[5]

Open surgical bypass has generally been supplanted as the first therapeutic option for mesenteric revascularization by endovascular treatment with angioplasty and intraluminal stents. Over the last decade, the number of endovascular procedures for mesenteric ischemia has increased tenfold, accounting for more than 70% of all initial revascularization procedures.[6,7] According to the Society of Vascular Surgery guidelines, endovascular revascularization (ER) is the preferred primary therapy, with open repair reserved for select younger patients and for those with lesions that are not amenable to endovascular therapy.[8,9]

Although the risk of recurring symptoms and the requirement for reintervention are both greater, the endovascular technique is linked to a lower perioperative complication rate and shorter inpatient hospital length of stay.[10–12] The perioperative mortality and long-term mortality, however, do not appear to differ between the endovascular and open procedures.[13,14]

Outcomes comparison between endovascular and open repair has been well reported in the literature; however, few studies have evaluated the cost and quality of life between the 2 interventions.[15,16] The cost per disability-adjusted life years associated with interventions has become an increasingly popular means to potentially assist healthcare professionals in selecting the most cost-effective intervention and policymakers to improve healthcare delivery in view of soaring healthcare costs in the United States.[17,18]

The most notable cost-effective analysis for CMI has been by Hogendoorn et al. which suggests that endovascular treatment is more cost-effective than open repair among all age groups, despite it being associated with greater projected reinterventions.[19] However, since the publication of this study, there has been an influx of new literature related to CMI. Therefore, we aim to present the latest cost-effectiveness analysis comparing open versus ER for CMI utilizing the updated outcomes and utilities from prospective studies.

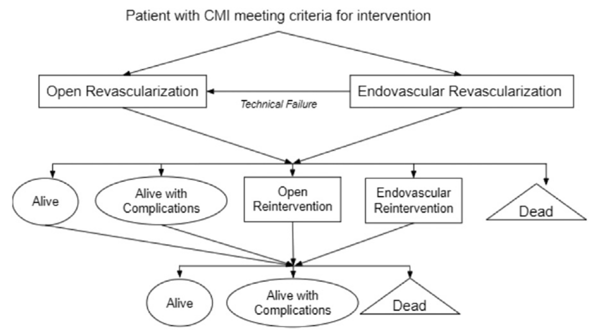

Fig. 1. Model state transition diagram.

METHODS

Cost-Effectiveness Model

We created Markov microsimulation models for patients with CMI meeting criteria for surgical intervention (Fig. 1, Supplemental Fig. 1). The model simulated the outcomes of 10,000 symptomatic patients randomized for either open revascularization (OR) or ER. All patients started in the health state corresponding to the intervention they were randomized to. If patients survived, they progressed to either ''alive after surgery'' or ''alive after surgery with complications'' depending on whether they experienced long-term complications. Patients in either alive state could experience loss of primary assisted patency and require a reintervention. If patients survived their reintervention, they progressed to either ''alive after surgery'' or ''alive after surgery with complications'' depending on their postoperative course. Unsuccessful ER were converted to OR and unsuccessful OR were converted to ER. Model outcomes were calculated on intent to treat basis.

The model used a 1-month cycle length and our base case extended over a 5-year time horizon. We performed model building and analyses using TreeAge Pro Healthcare (version 2020, Massachusetts).

Model Parameters

All probabilities used in this model were determined from peer-reviewed sources (Table I), using the highest level of evidence whenever possible. Effectiveness was measured in quality-adjusted life years (QALYs) which reflects the product of time and health utility. Health utility represents patient quality of life, which ranges from 0 (death) to 1 (perfect health), with each health state having a distinct health utility score.

Costs were determined from the hospital perspective utilizing the 2020 Medicare Physician Reimbursement Fee Schedule via Current Procedural

Table I. Parameters

Variable	Value	SD	Citation
Probabilities (beta distribution)			
Open revascularization			
Mortality (30-day)	0.055	0.011	Alahdab et al., 2018
In-hospital complications	0.543	0.109	Alahdab et al., 2018
Mortality (3 years)	0.233	0.047	Alahdab et al., 2018
Secondary patency (5 years)	0.979	0.196	Pecoraro et al., 2014
OR - > ER probability	0.404	0.081	Kanamori et al., 2014
OR - > ER complication	0.158	0.032	Kanamori et al., 2014
OR - > ER mortality	0.0001	0.0002	Kanamori et al., 2014
OR - > OR complication	0.679	0.136	Kanamori et al., 2014
OR - > OR mortality	0.220	0.044	Kanamori et al., 2014
Endovascular revascularization			
Mortality (30-day)	0.014	0.003	Alahdab et al., 2018
In-hospital complications	0.272	0.054	Alahdab et al., 2018
Mortality (3 years)	0.206	0.041	Alahdab et al., 2018
Secondary patency	0.736	0.147	Saedon et al., 2015
Conversion to open	0.036	0.0072	Zacharias et al., 2016
ER - > ER complication	0.270	0.054	Tallarita et al., 2011
ER - > ER mortality	0.030	0.006	Tallarita et al., 2011
ER - > OR probability	0.230	0.046	Zacharias et al., 2016
ER - > OR complication	0.679	0.136	Kanamori et al., 2014
ER - > OR mortality	0.150	0.030	Zacharias et al., 2016
Utilities (beta distribution)			
Baseline	0.700	0.140	Blauw et al., 2019
Open revascularization			
Postoperatively at 6 months	−0.032	−0.0064	Stroupe et al., 2012 (OVER trial)
Postoperatively at 1 year	−0.047	−0.094	Stroupe et al., 2012 (OVER trial)
Postoperatively at 2 years	−0.089	−0.178	Stroupe et al., 2012 (OVER trial)
Endovascular revascularization			
Postoperatively at 6 months	−0.029	−0.058	Stroupe et al., 2012 (OVER trial)
Postoperatively at 1 year	−0.05	−0.010	Stroupe et al., 2012 (OVER trial)
Postoperatively at 2 years	−0.07	−0.014	Stroupe et al., 2012 (OVER trial)
Complications	−0.26	−0.052	Cooper et al., 2020
Costs (in 2020 Dollars; gamma distribution)			
Open revascularization	1,975.30	395.06	HCPCS 35531
Endovascular revascularization	3,318	663.60	HCPCS 37236
Follow-up visit	92.47	18.49	HCPCS 99213
Follow-up imaging	284.03	56.81	HCPCS 93975
Complications (initial)	205.52	41.10	HCPCS 90962
Complications (repeat)	362.54	72.51	HCPCS 90960

OR, open revascularization; ER, endovascular revascularization; SD, standard deviation.

Terminology (CPT) codes. As 1 might expect, the outcomes associated with an intervention would vary over time, and to accurately reflect these changes we incorporated time-varying data into our model. Specifically, we incorporated time-varying values for the following: mortality after OR and ER, disutilities after OR and ER, and costs of long-term complications. Disutilities and costs for long-term complications were modeled after stage 3 chronic kidney injury, as kidney injury is 1 of the most common complications after CMI interventions.[6] Because of limitations in data availability, disutilities after OR and ER were approximated using EQ-5D questionnaire scores from the Open Surgery Versus Endovascular Repair of Abdominal Aortic Aneurysm (OVER) trial.[20]

Quality of Life Surrogate Studies

Previous literature has supported revascularization in patients with CMI suggesting significant improvement in quality of life.[4,21,22] Given there is no minimal clinically important difference established for CMI, Blauw et al. used literature from patients

Table II. Model validation

	Mortality		Secondary patency			
Revascularization method	30-Day	3-year	OR then OR	OR then ER	ER then ER	ER then OR
OR	5.60%	21.67%	0.82%	0.51%	-	-
ER	1.32%	20.51%			5.99%	1.78%

with inflammatory bowel disease to determine that revascularization in CMI improves health-related quality of life (HRQoL).[4]

For our model, we used the difference in quality of life after open abdominal aortic aneurysm (AAA) repair and endovascular repair. Literature has demonstrated that AAA repair is associated with a decreased quality of life, more pronounced in open repair compared to endovascular repair.[23] There are more quality of life studies on AAA repairs than CMI treatment, including level 1 meta-analysis and several studies comparing the cost of open versus endovascular repair of AAA and carotid artery stenosis, however, these report solely on the differences between techniques or cost, and does not take in to account cost effectiveness.[24–27] Given the limited cost effectiveness data for CMI, we used AAA studies to develop our model.

Finally, we used chronic kidney disease to determine long-term outcomes. For our population in the United States, prevalence of chronic kidney disease stages was updated to better represent our study.[28,29] We used the costs associated with chronic kidney disease stage 3, similar to Hogendoorn et al., but updated the Healthcare Common Procedure Coding System to include code 90,961—representing dialysis related services 2–3 times per month with a physician.[19] This was then used in our sensitivity analysis for complications. Mortality was able to be modeled from a meta-analysis in CMI of both OR and ER.[14]

Statistical Analysis

Cost effectiveness was assessed with an incremental cost-effectiveness ratio (ICER) which represents the incremental costs divided by incremental QALYs of each treatment group. ICERs under $100,000/QALY were considered cost-effective. Treatments that lowered costs and increased effectiveness were considered dominant. All costs and utilities were discounted by 3% annually to represent the concept that health utility is worth more to patients in the immediate time period rather than the future, and we used half-cycle corrections. We conducted one-way deterministic sensitivity analysis on all probabilities, utilities, and costs to determine their impact on cost-effectiveness. For all parameters, we used a reasonably wide range of values in our sensitivity analyses. We conducted probabilistic sensitivity analysis which included 100 microsimulations of 10,000 cases each where we modeled transition probabilities and health utilities with beta distributions, and costs with gamma distributions. We obtained standard deviations of model parameters from the literature whenever possible and used a standard deviation equal to 20% of the mean with unknown standard deviations. The study was conducted and published according to previously reported guidelines and prior similar literature.[30,31]

RESULTS

Model Validation

In our OR versus ER base-case microsimulation model among all comers with CMI, ER had lower 30-day and 3-year mortality compared to OR (1.32% vs. 5.60% and 20.51% vs. 21.67%), respectively. However, ER did have higher rates of reintervention (Table II).

Base Case Microsimulation

Our microsimulation model of OR versus ER found that OR cost health care systems $4,523 for 1.03 total QALYs versus $5,092 for 1.21 QALYs among ER patients. ER demonstrated greater QALYs but at higher prices, which corresponded to an ICER of $3,037 (Table III, Fig. 2).

Deterministic Sensitivity Analysis

We found that our microsimulation was sensitive to all cost parameters (Table IV). OR is cost-effective given the cost of OR is less than $5,000 (above our baseline estimate of $1,975.30). Our model was also sensitive to most probabilities, including the probability of complications, mortality, secondary patency, and conversion between ER and OR (Table IV).

Table III. Outcomes

Revascularization method	Total cost ($)	Incremental cost ($)	Total effectiveness (QALYs)	Incremental effectiveness (QALY)	ICER ($/QALY)
OR	4,532	-	1.03	-	-
ER	5,092	560	1.21	0.18	3,037

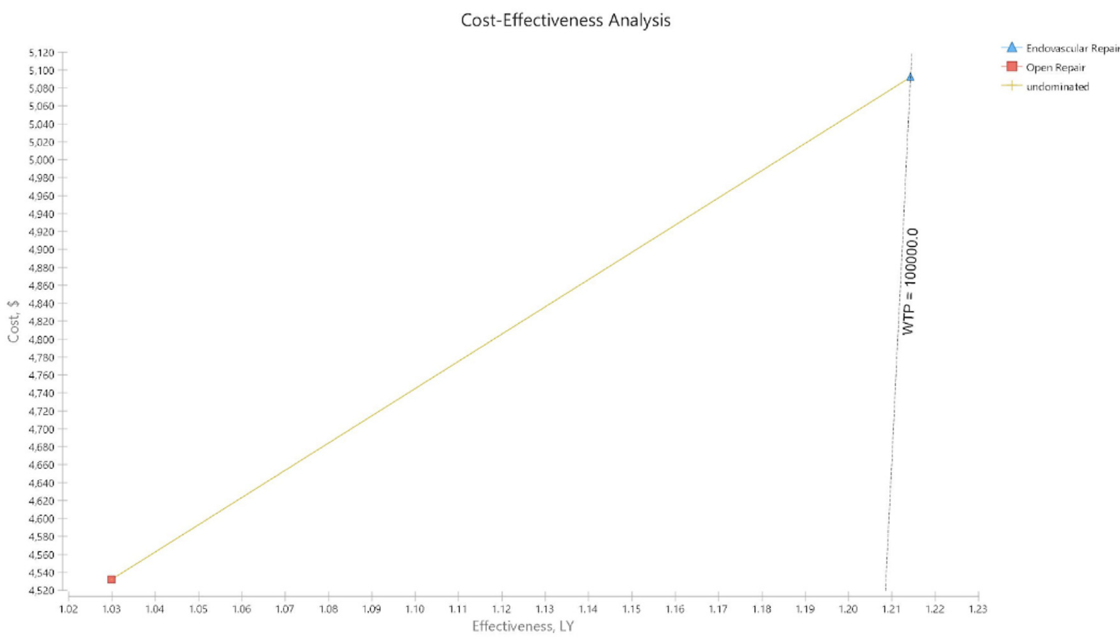

Fig. 2. Cost-effectiveness curve.

Probabilistic Sensitivity Analysis

Our probabilistic analysis found that ER was found to be cost-effective in over 99% of all cases using a willingness-to-pay threshold of $100,000/QALY (Fig. 3).

DISCUSSION

This study uses a microsimulation model to compare the cost, efficacy, and cost effectiveness of OR versus ER in CMI. Even though 5-year costs were $560 more in ER versus OR, ER provided a greater QALY. This is 1 of the first studies in the literature that compares OR versus ER in the treatment of CMI for cost effectiveness.

To date, there are 3 studies that assess HRQoL; however, these were not included in our model. Blauw et al. did not stratify between OR versus ER, acute on chronic presentation versus chronic, or etiology (atherosclerosis versus median arcuate ligament syndrome [MALS]).[4] Similarly, Skelly et al. found improvement in quality of life, but only assessed patients with MALS, while Wagenhauser et al. retrospectively reviewed patients with CMI to assess HRQoL, but did not include a baseline for comparison.[21,22]

In terms of the AAA data, we initially assessed the Dutch Randomised Endovascular Aneurysm Management (DREAM) trial, but decided against it due to the study being concentrated in Europe which has different healthcare models than the United States and individuals have different access to health resources.[32] Ultimately, we modeled our study using the Virginia (VA) population with the OVER trial due to its contemporary nature and data that was stratified by time with specific outcomes for the open and endovascular groups.[20,33] While we were initially concerned about the generalizability of the OVER trial to the broader US population given the OVER trial consists of men from the VA, we found that the clinic risk factors of increased age, dyslipidemia, hypertension, and cardiovascular disease which are most commonly affected by CMI are similar to the VA population and confirmed on sensitivity analysis.[14]

Table IV. One-way sensitivity analysis

Variable	Base value	Lower bound	Upper bound
Costs (in 2020 dollars; gamma distribution)			
Open revascularization	1,975.30	1	5,000
Endovascular revascularization	3,318	1	5,000
Follow-up visit	92.47	1	1,000
Follow-up imaging	284.03	1	1,000
Complications (initial)	205.52	1	1,000
Complications (repeat)	362.54	1	1,000
Probabilities (beta distribution)			
Open revascularization			
In-hospital complications	0.543	0.1	0.9
Mortality (3 years)	0.233	0.1	0.9
Secondary patency (5 years)	0.979	0.00001	0.9
OR - > ER probability	0.404	0.1	0.9
OR - > ER complication	0.158	0.1	0.9
OR - > ER mortality	0.0001	0.1	0.9
OR - > OR complication	0.679	0.1	0.9
OR - > OR mortality	0.220	0.1	0.9
Endovascular revascularization			
Mortality (30-day)	0.014	0.001	0.95
In-hospital complications	0.272	0.001	0.95
Mortality (3 years)	0.206	0.001	0.95
Secondary patency	0.736	0.001	0.95
Conversion to open	0.036	0.001	0.95
ER - > ER complication	0.270	0.001	0.95
ER - > ER mortality	0.030	0.001	0.95
ER - > OR probability	0.230	0.001	0.95
ER - > OR complication	0.679	0.001	0.95
ER - > OR mortality	0.150	0.001	0.95

In order to assess for long-term complications, we used chronic kidney disease quality of life metrics, as previously done in similar studies.[19,34] In terms of patency, we assumed that primary assisted patency was synonymous with secondary patency.[35] Additionally, given the limited data in CMI we had to use values from OR to OR complications as surrogates for ER to OR complications.[36]

Furthermore, we did not discuss individual differences between the various types of ER procedures.[37–39] The Covered stent versus Bare-metal stens in chronic atherosclerotic Gastrointestinal Ichemia (CoBaGI) study was a randomized trial protocol to assess the differences between covered and bare-metal stents in atherosclerotic disease in general.[40] An assumption in our model was that first line reinterventions in both arms were endovascular interventions and given the data, we only allowed patients to have 2 interventions at most.[8] Advances in CMI treatment have led to hybrid procedures, such as retrograde open mesenteric stenting as a new revascularization method. However, we were unable to include this in our model. Currently, there are no randomized controlled trials demonstrating this technique and current literature contains small sample sizes.[41] Additionally, there is little data on long-term outcomes with only a few studies discussing patency at 1-year or 2-years.[41,42] With the limited data available, it is difficult to extrapolate quality of life (QoL) outcomes from these hybrid procedures, while it is possible that perioperative outcomes may be comparable.

Compared to Hogendoor et al. our utilities were adjusted as indicated above.[19] However, Hogendoor et al. did not include the cost of follow-up ultrasound imaging in his model.[19] Our schedule was in concordance with the follow-up schedule described by Society for Vascular Surgery guidelines which includes an ultrasound at 1 month, biannually for 2 years and then annual thereafter.[8,9]

Overall, our results indicate that when treating CMI, ER is more cost effective than OR, even after considering patency and reintervention. As ER is becoming more common across the specialty, it is important to ensure that there remains benefit to patients over more traditional OR. The aim of this study was to assess the cost effectiveness of CMI treatment. In regards to clinical application, we hope this study offers clinicians more data to provide

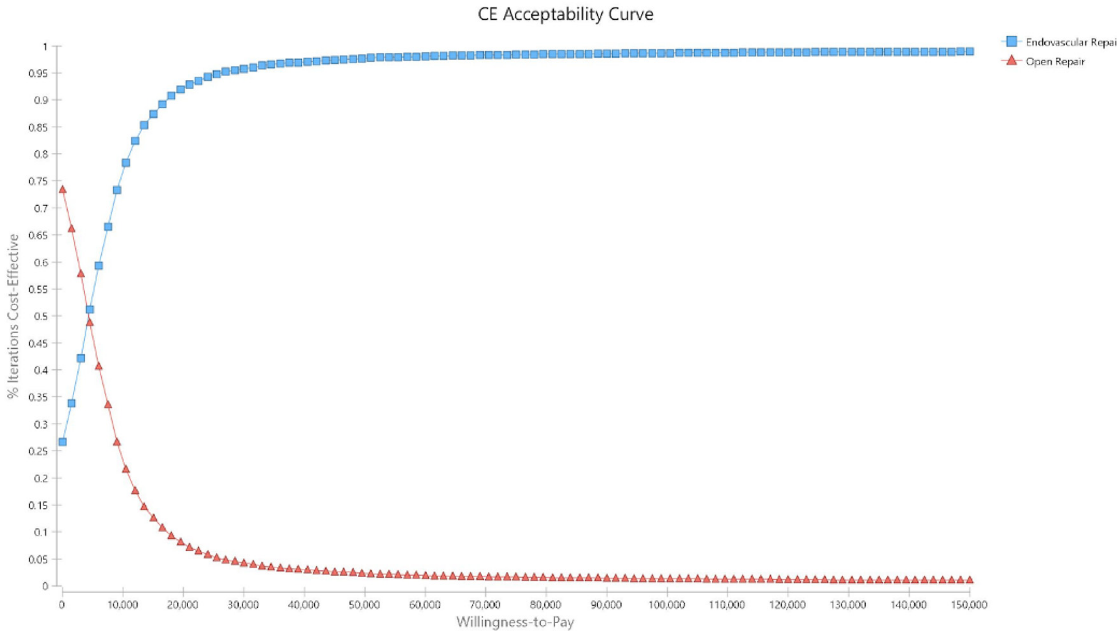

Fig. 3. Probabilistic sensitivity analysis.

patients when discussing OR versus ER options. Although OR has traditionally been the treatment of choice in CMI, this study shows that ER is more cost-effective and allows greater QALYs.

Limitations

Our study has several limitations. Overall, the data is not granular or detailed enough to quantify procedural risk, outcomes, cost, or health utilities by number of vessels involved in a patient's CMI. This is likely due to the fact that our data comes from multiple other studies without access to the raw data. Furthermore, our study is unable to quantify the impact the diagnosis of CMI has on the entire family. Current literature from AAA disease suggests that chronic vascular illnesses have significant effects not only on the patient, but the family as well, including QoL.[43] Finally, in terms of our cost assessment, we did have to use physician reimbursement as a surrogate for hospital cost. Using CPT codes from Medicare physician fees was also done by Hogendoorn et al. in his assessment of the cost of OR versus ER in CMI.[19] This surrogate is not as accurate to represent the global view of costs for a particular procedure; however, it is considered the standard.

CONCLUSION

Cost-effectiveness has become a more important factor in healthcare as costs continue to rise. However, a patient's quality of life is seldom assessed and factored into decision making. While 5-year costs for ER were greater than OR and ER is associated with lower long-term patency and higher rates of reintervention, the ER afforded greater QALYs than OR. Therefore, we believe for patients with CMI, ER is more cost effective than OR.

SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.avsg.2023.02.013.

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