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ORIGINAL ARTICLE

Surgical correction of the genital hiatus at the time of sacrocolpopexy — a 7-year Markov analysis: a cost-effectiveness analysis

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Abstract

Introduction and hypothesis To perform a cost-effectiveness analysis of concurrent posterior repair performed at the time of laparoscopic hysterectomy with sacrocolpopexy over a 7-year time period. We hypothesize it is not cost-effective to perform a posterior colporrhaphy.

Methods We used TreeAge Pro® to construct a decision model with Markov modeling to compare sacrocolpopexy with and without concurrent posterior repair (SCP and SCP+PR) over a time horizon of 7 years. Outcomes included probability and costs associated with prolapse recurrence, prolapse retreatment, and complications including rectal injury, rectovaginal hematoma requiring reoperation, and postoperative dyspareunia. Cost-effectiveness was defined as an incremental cost-effectiveness ratio (ICER) calculated as Δ costs /Δ effectiveness and the willingness to pay (WTP) was set at $100,000/QALY.

Results Our model showed that SCP was the dominant strategy, with lower costs (−$ 2681.06) and higher effectiveness (+0.10) compared to SCP+PR over the 7-year period. In two-way sensitivity analyses, we varied the probability of prolapse recurrence after both strategies. Our conclusions would only change if the probability of recurrence after SCP was at least 29.7% higher than after SCP+PR. When varying the probabilities of dyspareunia for both strategies, SCP+PR only became the dominant strategy if the probability of dyspareunia for SCP+PR was lower than the rate of SCP alone.

Conclusions In this 7-year Markov cost-effectiveness analysis, SCP *without* concurrent PR was the dominant strategy. SCP+PR costs more with lower effectiveness than SCP alone, due to higher surgical cost of SCP+PR and higher probability of dyspareunia after SCP+PR.

Keywords Genital hiatus · Sacrocolpopexy · Perineorrhaphy · Posterior repair · Pelvic organ prolapse · Prolapse recurrence

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Introduction

Sacrocolpopexy (SCP) is a highly successful surgical treatment option for pelvic organ prolapse [1]. While surgical retreatment after SCP is uncommon, those with a pre-operative genital hiatus size of > 4cm had nearly twice the odds of prolapse recurrence [2]. In addition, patients who had a concurrent posterior colporrhaphy at the time of sacrocolpopexy had less odds of prolapse recurrence [2].

Despite retrospective evidence supporting a concurrent posterior repair at the time of SCP, there is a paucity of robust prospective data demonstrating improvement of surgical outcomes with a concurrent posterior repair. Coupled with concerns over post-operative dyspareunia [3–9] and surgical complications directly related to a posterior repair, some surgeons do not routinely perform a concurrent posterior repair at the time of sacrocolpopexy.

Our group previously analyzed this question with a cost-effectiveness analysis comparing two treatment strategies: laparoscopic hysterectomy with sacrocolpopexy versus laparoscopic hysterectomy with sacrocolpopexy and posterior repair. We demonstrated in the 1-year cost-effectiveness model that sacrocolpopexy alone was the cost-effective approach compared to sacrocolpopexy with concurrent posterior repair [10].

For most patients, surgical correction of prolapse will lead to an overall reduction of dyspareunia with an improvement in sexual function over time [5, 11, 12]. Evaluating sexual function over a longer time period after the index surgery may provide a more clinically relevant analysis of the utility of a concurrent posterior repair at the time of sacrocolpopexy. Furthermore, the probability of prolapse recurrence increases over time. Currently, the study with the longest patient follow-up time comparing SCP alone to SCP with posterior repair is 7 years allowing for creation of a model with a time horizon beyond 1 year [13]. This study showed that in patients with asymptomatic rectoceles, a concurrent posterior repair at the time of SCP reduces the odds of failure based on a composite patient-centered outcome.

As a result, our objective was to perform a cost-effectiveness analysis of concurrent posterior repair performed at the time of laparoscopic hysterectomy with sacrocolpopexy over a 7-year time period.

Materials and methods

We constructed a Markov cost-effectiveness decision model using TreeAge Pro® 2020 (TreeAge Software, Williamstown, MA, USA) comparing two treatment strategies: laparoscopic hysterectomy with sacrocolpopexy (SCP) versus laparoscopic hysterectomy with sacrocolpopexy and concurrent posterior repair (SCP+PR) over a 7-year time horizon. This time horizon was chosen as this was the mean time period patients were followed in the largest retrospective cohort study comparing sacrocolpopexy surgical outcomes with and without posterior colporrhaphy [13]. The 7-year Markov model was designed based on the 1-year cost-effectiveness analysis comparing the two treatment strategies. The clinical treatment pathways after surgery were modeled based on consensus of the author group, which includes five fellowship-trained female pelvic medicine and reconstructive surgeons from five different institutions (Fig. 1) [10]. To account for differences in technique and nomenclature regarding what is considered a posterior repair, we defined a single category of posterior repair to include posterior colporrhaphy with plication of midline fibromuscular layer and/or perineal repair with reconstruction of the perineal body (also known as perineorrhaphy) [14].

The hypothetical patient cohort was a population of healthy women with uterovaginal prolapse without outlet defecatory dysfunction. Patients with outlet defecatory dysfunction were excluded, as a posterior colporrhaphy would potentially be performed to address the defecatory dysfunction rather than as an additional surgical option to decrease prolapse recurrence. All probabilities were obtained from existing literature. If multiple studies were available, a weighted average for the target variable was calculated (pooled number of patients with the outcome of interest/pooled number of total patients).

Immediately after surgery, we modeled the possibility of developing immediate post-operative complications and adjusted the patient quality of life using utilities in the event of a complication. For the Markov modeling, patients entered the Markov model at 1 year. Upon entering the Markov cycle, based on established probabilities, patients may or may not have developed post-operative complications and/or dyspareunia. For those patients with dyspareunia, treatment is initiated at the time of diagnosis prior to entering the Markov cycle at 1 year. With the Markov analysis set at 1-year cycles, all patients could develop prolapse recurrence, need prolapse retreatment, and have improved or persistent dyspareunia based on the probabilities we obtained. Patients who do not develop these complications are cycled annually through the 7-year time horizon.

For immediate post-operative complications, the model only included complications associated with a posterior repair, since the two treatment strategies only differed by whether a posterior repair was performed or not. Any complications related to a hysterectomy or SCP would be equivalent between the two treatment strategies and would not impact the primary outcome variable of the incremental cost-effectiveness ratio (ICER), as there would be no difference in the impact on costs or quality-adjusted life-years (QALYs). For example, it is possible that the SCP could result in a distal rectal injury. However, any costs or impact on the quality of life related to a hysterectomy or SCP complication would impact both strategies equally and ultimately not affect the ICER, which is a measurement of the delta/difference in costs and effectiveness.

In the SCP+PR treatment arm, immediate post-operative complications included rectal injury and rectovaginal hematoma. Table 1 shows the probabilities and ranges of all the variables in this model. For rectal injury, we assumed that the rectal injury would be identified intraoperatively. Because most rectal injuries associated with posterior repairs are located in the distal rectum, we assumed that the surgeon performing the surgery could repair it. For this complication, we assumed surgical costs would increase the operative and anesthesia time by ≥ 30 minutes. The weighted probability of rectal injury of 0.38% (range 0–0.95%) was calculated

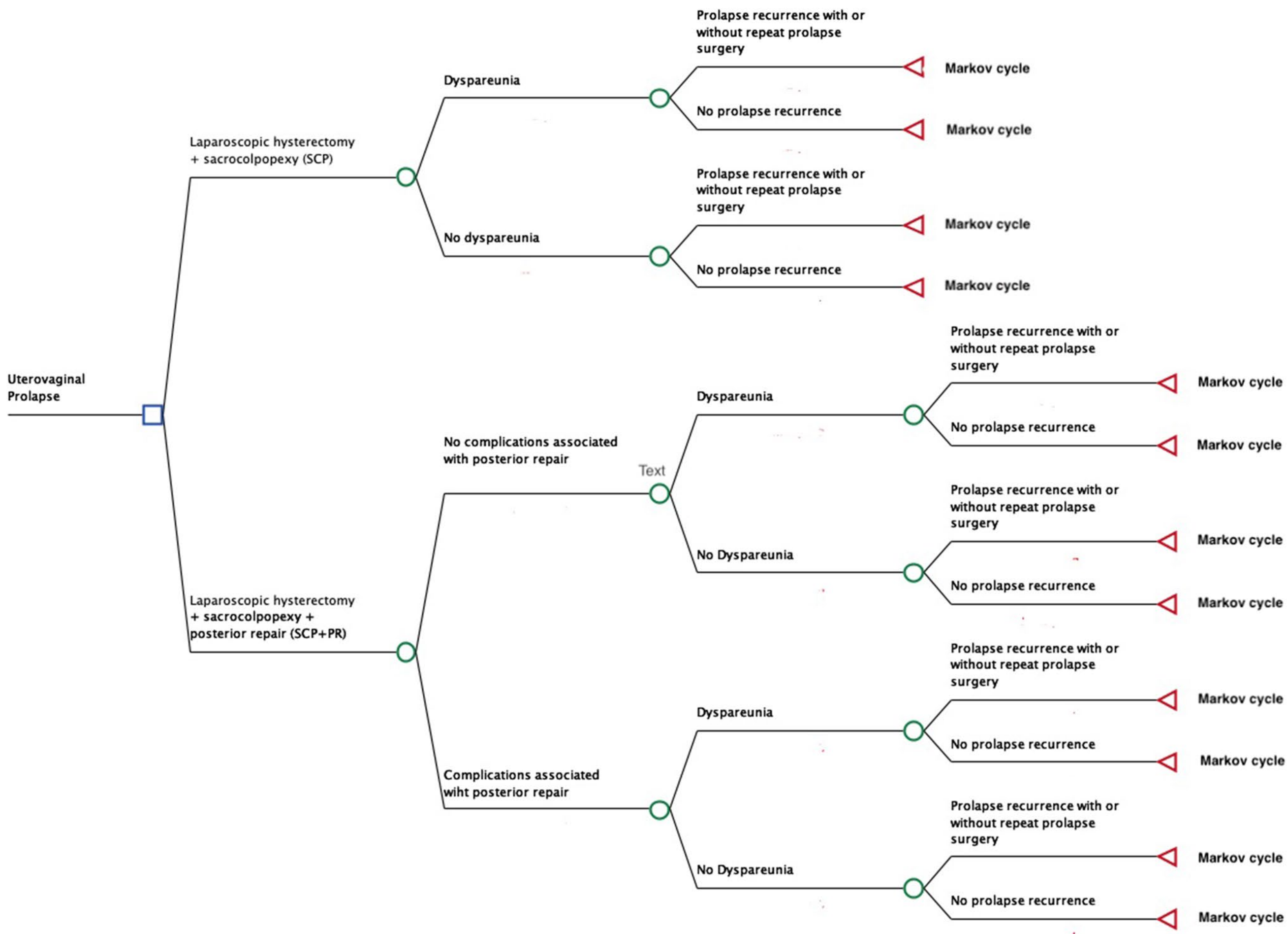

Fig. 1 Simplified cost-effectiveness analysis tree comparing sacrocolpopexy alone versus sacrocolpopexy with posterior repair

from four studies that reported rectal or gastrointestinal injuries at the time of prolapse surgery [6, 15–17].

For rectovaginal hematoma, we assumed the development of a clinically significant hematoma impacting function which would require surgical evacuation. For the hematoma evacuation, we assumed that this operation would occur during the same admission as the index surgery, and the surgery to evacuate the hematoma would take 30 minutes of operative and anesthesia time. The probability of rectovaginal hematoma was determined based on one randomized controlled trial which reported a rectovaginal hematoma rate of 0.95% [6]. Given input from only one study, we varied the probability of post-operative hematoma from 0–100% in our sensitivity analysis to evaluate the potential for heterogeneity in our data inputs.

We modeled that some patients would develop dyspareunia after either treatment strategy. We designed the treatment of dyspareunia to include vaginal estrogen cream (four tubes x $200/tube) and pelvic floor physical therapy (six x 1-hr sessions) to total $1889 in a given year. For patients in the SCP group, we used data from two studies to determine a post-SCP dyspareunia rate of 18.5% (range 17–19%) [5, 18]. For patients in the SCP+PR group, we averaged the probability of developing post-operative (persistent and de novo) dyspareunia after PR from seven studies as 26.5% (range 7–36%) [3–9]. We recognize that there are varying techniques to a posterior repair, and the dyspareunia rate may also vary from study to study based on the definition of dyspareunia used. As with all the other variables of interest in the model, we varied the probability of post-operative dyspareunia from 0–100% in our sensitivity analysis to evaluate the potential for heterogeneity in our data inputs.

In the Markov analysis over the 7-year period, we assumed that the adherence rate to use of vaginal estrogen is 28% based on two studies (range 10.6–46%) at 1 year [19, 20]. For those who are adherent to treatment, we assumed that there is a 90% improvement in symptoms over a 1-year period, with improvement in QALYs [21, 22]. For those with persistent dyspareunia despite treatment adherence at 1 year, we assumed that they will discontinue any further treatment and have persistent dyspareunia across the 7-year time horizon.

Table 1 Model probabilities

Variable	Probability	Range in literature	References
Probability of rectal injury after SCP+PR	0.0038	0–0.0095	[6, 15–17]
Probability of hematoma at after SCP+PR	0.0095	0.0095	[6]
Probability of dyspareunia after SCP+PR	0.27	0.07–0.36	[3–9]
Probability of dyspareunia after SCP	0.19	0.17–0.19	[5, 18]
Probability of prolapse recurrence after SCP+PR	0.058	0.048–0.063	[13, 23]
Probability of prolapse recurrence after SCP	0.092	0.068–0.135	[13, 23]
Probability of prolapse retreatment after SCP+PR	0.021	0.019–0.024	[13, 23]
Probability of prolapse retreatment after SCP	0.048	0.042–0.06	[13, 23]
Probability of 1-year treatment adherence to vaginal estrogen	0.28	0.011–0.46	[19, 20]

SCP sacrocolpopexy, *SCP+PR* sacrocolpopexy with concurrent posterior repair

The probability of prolapse recurrence was determined based on two studies that directly compared prolapse recurrence between the SCP and SCP+PR groups [13, 23], with prolapse recurrence of 9.2% (range 6.8–13.5%) for SCP alone, compared to 5.8% (range 4.8–6.3%) for SCP+PR. Of those who developed prolapse recurrence, we assumed that a subset would desire surgical retreatment. The probability of repeat surgery after SCP was 4.8% (range 4.2–6%) and for SCP+PR was 2.2% (range 1.9–2.4%) [13, 23]. An annualized rate of occurrence was calculated for the above variables over the 7-year period. The compartment of prolapse recurrence after prolapse surgery can vary from the anterior, apical and/or posterior compartments, and there is no standard surgery to treat prolapse recurrence [13, 24]. To account for the different compartments which may need to be surgically corrected and surgeon preferences, we modeled an evenly weighted average of the surgical costs of a repeat sacrocolpopexy (open or laparoscopic), vaginal uterosacral ligament colpopexy, and vaginal sacrospinous ligament.

Quality-adjusted life years (QALY) were calculated by taking a weighted average of the utility values and the proportion of patients who follow specific pathways over the 7-year time horizon. We assigned health state utility values based on the literature for prolapse health states, complications, dyspareunia with and without treatment, and prolapse recurrence (Table 2). For each given year, a utility score of 0 represented a health state equivalent to death and a score of 1 represented perfect health. Over the 7-year period, the minimum health utility or effectiveness score was 0 and maximum was 7 measured in QALYs. Based on published estimates, we assigned a health-state utility value to living with pelvic organ prolapse (0.83), successful prolapse surgery (0.88) and failed prolapse surgery (0.75) [25, 26]. If a second prolapse surgery was needed, we assumed that the patient would receive the same incremental gain of QALY as the primary prolapse repair (+0.05). In the event of complications, we assigned a −0.19 loss in health state utility for both hematoma and rectal injury [27]. For dyspareunia, we assigned a health disutility value of −0.17 [28]. With dyspareunia treatment, we assumed a +0.07 gain in QALY from the initial disutility of dyspareunia [28, 29].

Costs were obtained from several sources, including Stanford University Hospital institutional charges. These charges are what is typically billed to insurance providers after surgery for each procedure and we applied a charge-to-cost ratio to determine cost for surgeries. We selected a charge-to-cost ratio of 0.24 based on the authors' collective experience at different academic institutions. Recognizing varying cost–charge ratios, we performed a sensitivity analysis ranging the ratio from 0.18 to 0.30. The use of institutional billing data allowed us to gather granular charges such as costs associated with operating room time, anesthesia time, and of disposable equipment.. Costs for vaginal estrogen was obtained from online pharmacies, and costs for pelvic floor physical therapy was obtained from Medicare. We assumed a discount rate of 3% for the costs. All costs are listed in Table 2 and are reported in 2019 US dollars ($).

A strategy with lower costs and higher effectiveness is intuitively cost-effective. We say that the more costly and less effective strategy is "dominated". However, there are many scenarios where a strategy may have higher costs and also higher effectiveness. In this scenario, cost-effectiveness is determined by comparing the incremental cost-effectiveness ratio (ICER) for each treatment strategy. The ICER, our primary outcome for this analysis, is calculated as the difference in cost divided by the difference in effectiveness (delta cost/delta effectiveness). In this analysis, the ICER was calculated over 7 years. Strategies are considered cost-effective when the ICER is less than the willingness to pay (WTP) threshold of $100,000/QALY.

Multiple sensitivity analyses were performed to determine whether changes to the model's input parameters would change the overall conclusions of the cost-effectiveness model. All base-case input variables were varied across a range (costs 20–200%, probabilities 0–100%, utilities 0–1.00, cost–charge ratio 0.18–0.30) to predict whether outcomes would change. Tornado plots were generated, and two-way sensitivity analyses were also performed.

Table 2 Model health utility values and costs

Variable	Probability	References
Health utility value of pelvic organ prolapse	0.83	[26]
Health utility value of successful pelvic organ prolapse surgery	0.88	[26]
Health utility value of failed pelvic organ prolapse surgery	0.75	[25]
Health utility value of a repeat pelvic organ prolapse surgery	0.83	[26]
Health utility gained with dyspareunia treatment	+0.07	[28, 29]
Health utility decrement of untreated dyspareunia	–0.17	[28]
Health utility decrement of rectovaginal hematoma requiring surgical evacuation	–0.19	[27]
Health utility decrement from a rectal injury requiring surgical repair	–0.19	[27]
Cost of SCP	$15,633	*
Cost of SCP+PR	$17,780	*
Cost of repeat prolapse surgery	$12,163	*
Cost of hematoma	$9,106	*
Cost of rectal injury	$3,108	*
Cost of dyspareunia treatment	$1,889	[30, 31]

SCP sacrocolpopexy, *SCP+PR* sacrocolpopexy with concurrent posterior repair

*Stanford University Hospital institutional costs with a 0.24 charge-cost ratio applied

Results

Sacrocolpopexy (SCP) was the dominant strategy, with a 7-year cost of $16,712 and an effectiveness of 6.79. Sacrocolpopexy with posterior repair (SCP+PR) cost more at $19,393 (difference $2,681), with an effectiveness of 6.69. Since SCP had lower costs and higher effectiveness outcomes over the 7-year period, it is the dominant and therefore cost-effective strategy. As a result, an incremental cost-effectiveness ratio was not necessary. The difference in effectiveness between the two strategies did not exceed the minimal important difference in healthy utility values [32]. Over 7 years, 67.4% of patients in the SCP+PR arm in the model had lack of both complications and prolapse recurrence, compared to 72.9% of patients in the SCP arm. Most complications in the SCP+PR arm were due to dyspareunia.

Tornado plots showed CEA results were most influenced by the cost of SCP and cost of SCP+PR. On one-way sensitivity analysis, our model would change if the cost of SCP+PR is less than that of SCP alone. This is not realistic given the additional operative and anesthesia time required for the concurrent posterior repair. Even if the addition of the posterior repair does not extend operative time, as in the case of performing the posterior repair at the time of port site closure, it is not possible for the SCP+PR procedure to cost less than SCP alone.

In our two-way sensitivity analyses, the probabilities of dyspareunia and prolapse recurrence were compared between the two strategies. The probabilities of dyspareunia after SCP and SCP+PR were varied against each other, and our conclusions would only change if the probability of dyspareunia after SCP was higher than that after SCP+PR. When the probabilities of prolapse recurrence after either index surgery were varied simultaneously, our conclusions would only change if the probability of recurrence after SCP was at least 29.7% higher than our base case of SCP+PR (base case difference 3.4%). Overall, it is not reasonable to assume that dyspareunia rates would be higher in the absence of a posterior repair, and we also do not believe that the recurrence rates could vary by nearly 30%. As such, we concluded that our modeling was robust based on the above sensitivity analyses.

Discussion

In this 7-year Markov cost-effectiveness analysis, SCP alone was the dominant strategy, with lower costs and higher effectiveness. SCP+PR had higher costs due to longer operative and anesthesia time, as well as the increased costs from immediate post-operative complications and long-term complications such as dyspareunia.

Over a 7-year time period, the difference in effectiveness between the two strategies remained comparable between the two strategies as the difference. If cost of treatment was not a consideration, the decision to proceed with or without concurrent posterior repair should be dependent on the patient's preferences to avoid surgical complications, including dyspareunia, or to minimize prolapse recurrence.

When designing this cost-effectiveness analysis, we assumed that all patients in the SCP+PR arm would receive a posterior repair. In the absence of robust data on a "target" intraoperative resting genital hiatus size at the time of sacrocolpopexy, we were unable to include this in our model without data demonstrating how the addition of a posterior repair improves prolapse outcomes stratified by genital hiatus size. However, in real-life, the decision to perform a concurrent posterior repair in a patient without defecatory dysfunction may depend on the size of the genital hiatus after sacrocolpopexy. Extrapolating data from two studies looking at intraoperative resting genital hiatus size at the time of native-tissue prolapse surgeries, those with an immediate post-operative resting genital hiatus of < 3 and < 3.5cm had less odds of developing surgical and/or anatomic recurrence [33, 34]. In other words, while our findings suggest that SCP is the cost-effective and preferred option, there may be clinical scenarios where there is an enlarged intraoperative resting genital hiatus even after apical suspension. In these patients, there may be some benefit to perform a concurrent posterior repair to optimize level 3 pelvic organ prolapse support.

Retreatment rates are low after sacrocolpopexy, but in those who do require retreatment, 36–50% of patients subsequently undergo a posterior colporrhaphy [13, 24]. Considerations could be made towards a staged approach for a posterior repair only if there is a development of a symptomatic rectocele, or a targeted approach for a concurrent posterior repair only when there is a persistently enlarged genital hiatus size.

Apart from the increased operative time and surgical risks associated with a posterior colporrhaphy, a posterior colporrhaphy can increase the risks of post-operative dyspareunia. In our analysis, we applied a probability of post-operative persistent or de novo dyspareunia of 26.8% for the SCP+PR, which is based on several studies with a rate ranging from 7–36% [3–9]. Because this probability may be higher than perceived by most surgeons, we varied this probability from 0–100%, and this did not change our conclusions that SCP is the dominant option and therefore cost-effective. We did not include costs of other treatment for dyspareunia such as vaginal CO2 laser therapy or surgical revision; these additions would only increase the cost of dyspareunia treatment, to further bolster our conclusion that SCP alone is the preferred option.

Our study is not without limitations. For cost-effectiveness analyses, there may be concerns over what costs are used and thus its generalizability. We did utilize institutional charges with conversion to costs for the advantage of calculating granular costs such as operating room time or prolonged anesthesia time. While institutional costs may be higher than Medicare costs, because we are comparing only the difference of a concurrent posterior repair between two otherwise identical surgeries, the use of institutional costs should not change our conclusions.

The strength of this study is the analysis of this clinically relevant question with a cost-effectiveness analysis over the long-term. All the probabilities were obtained based on the literature and tested against multiple sensitivity analyses. The Markov analysis treatment pathway was designed based on the consensus of multiple fellowship-trained urogynecologists at different geographic locations to represent a wide variety of practice patterns.

Conclusion

In summary, in this 7-year Markov cost-effectiveness analysis, we found that SCP is the dominant and therefore cost-effective treatment strategy for uterovaginal prolapse compared to SCP+PR. The effectiveness was similar between the two strategies, and most patients will have surgical success without complications if they undergo SCP alone.

Contributions to authorship OC, JS, BM, ES, SW — Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.

OC, JS, BM, ES, SW — Drafting the work or revising it critically for important intellectual content.

OC, JS, BM, ES, SW — Final approval of the version to be published.

OC, JS, BM, ES, SW — Agreement to be 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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Declarations

Ethics approval Not applicable since the study was based on modeling and previously published data.

Conflicts of interest None.

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