Use of the Ring Wound Protector in Open Appendectomy: A Model-Based Cost-Utility Analysis

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Objective: To evaluate cost-effectiveness of ring wound protector (RWP) used in open appendectomy.

Materials and Methods: The present study was a decision-tree-based analysis. Model inputs, including costs, utilities, and probabilities of surgical site infection (SSI), were retrieved from the previous studies. The incremental cost-effectiveness ratio (ICER) represented the cost of one additional quality-adjusted life day (QALD). This ratio was calculated by dividing the incremental cost [Thai Baht (THB)] by the incremental QALD. One-way sensitivity analyses were performed by varying each input parameter to see how ICER change. Monte-Carlo simulation with 5,000 replications was used to estimate probabilistic ICER and construct the acceptability curve, demonstrating how the probability of being cost-effective changed when the willingness-to-pay (WTP) threshold was shifted.

Results: The deterministic ICER of 64,630.78 THB/QALD did not favor RWP use compared with the WTP threshold of 10,000 THB/QALD. However, if the threshold was shifted to 100,000 THB/QALD, it would yield approximately 75% probability of being cost-effective from RWP. Threshold analysis indicated that RWP should cost 281, 301, and 661 THB to be cost-effective at the threshold of 500, 1,000, and 10,000 THB/QALD, respectively.

Conclusion: Routine RWP use might not be cost-effective when QALD is the outcome of interest. Based on the results from the present study, policy-makers could be informed that the adoption of this health technology might not be suitable.

Keywords: Ring wound protector; Appendectomy; Cost-utility analysis; Decision tree model

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Appendicitis is one of the common surgical diseases, corresponding to 100 to 150 cases per 100,000 person-years⁽¹⁾. Appendectomy is the standard treatment for this condition. However, seven cases of surgical site infection (SSI) can occur in every 100 appendectomies. In upper-middle-income countries (like Thailand), the SSI rate could be as high as 8.5 cases per 100 appendectomies⁽²⁾.

SSI affects patients directly by increasing the reoperation rate and length of hospital stay^(3,4). SSI could also increase overall treatment cost up to

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\$34,000 per case⁽⁵⁾. Therefore, any attempt at reducing the SSI rate is significant. A wound protector, applied at the incision to protect it from contamination, is another strategy to prevent SSI. Meta-analyses⁽⁶⁻¹⁰⁾ indicated that using wound protectors associated with a 30% to 45% reduction of SSI in abdominal surgery. When wound protector was applied at appendectomy wound, 56% lower SSI rate could be observed⁽¹¹⁾.

However, routine use of wound protectors might increase treatment costs. As a result, the costeffectiveness of this equipment must be studied before adopting this technology in routine practice, especially in low to middle-income countries. The present study aimed to evaluate the cost-effectiveness of wound protectors using the decision tree model. The outcome of interest was a utility that could be used for comparison across various kinds of technology. Results from the present study could be beneficial for policy-makers.

Materials and Methods

The present study was approved by the Institute's Ethic Committee (COE 012/2021X). The present

study was a decision tree-based cost utility analysis undertaken from the societal perspective. The outcome was measured as quality-adjusted life days (QALDs). According to CDC's criteria⁽¹²⁾ for diagnosis of SSI, a time horizon was set to be 30 days. Therefore, no discounting was applied for costs and QALDs. The present study was reported in line with the CHEERS guideline⁽¹³⁾.

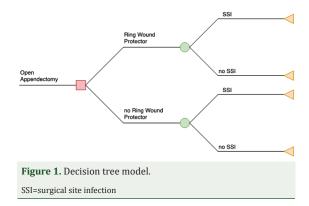
Model structure

The decision tree model consisted of nodes and branches. Nodes in the model could be a decision, chance, or terminal node. The decision node, symbolized by the square, was where treatment options were available for a decision to be made. Circle nodes, or chance nodes, represented uncertainty in which more than one event could occur with different probabilities. Terminal nodes (triangles), locating at the end of each path, were associated with the costs and utilities. Each branch connecting between nodes represented the path of events. Costs and QALDs for each treatment decision could be calculated by backward summation of the product between costs or utilities and probabilities of having events along each path.

The population of interest was appendicitis patients who underwent open appendectomy. The present model aimed to compare the two treatment options, appendectomy with or without a ring wound protector (RWP). The model assumed that following each treatment could be recovered with or without SSI occurrence, see Figure 1. Probabilities of SSI following RWP and no RWP uses were retrieved from the meta-analysis of Ahmed et al⁽¹¹⁾, the only available meta-analysis studying the effectiveness of RWP for SSI prevention in open appendectomy. The probability of SSI in RWP use was 0.039, whereas it was 0.117 when no RWP was applied. The model also assumed that all patients recovered without long-term consequences. Due to their rarity, death and other adverse events were not considered in the model.

Costs and utilities

The present study acquired costs and utilities from Siribumrungwong et al's study⁽¹⁴⁾, conducted between November 2012 and February 2016. The study had been selected as a source of cost and utility parameters because it enrolled a large sample size with 607 participants from six centers across Thailand. Total cost was the summation of direct medical, direct nonmedical such as informal care and transportation, and indirect costs such as income loss of the patients and



caregivers. Costs that occurred during hospitalization and after discharge were counted. Average treatment cost [Thai Baht (THB)] was calculated separately for SSI and non-SSI patients. A total treatment cost of 9,282.81 and 5,936.48 THB was used in the model corresponding with appendectomy with and without SSI, respectively. The costs were adjusted to be a value in June 2021 using the customer price index. Two thousand eight hundred fifty Baht, which is the cost of RWP in the present study hospital, was added to the cost for RWP.

At 30 days after an appendectomy, quality of life was measured by EQ-5D-5L questionnaire⁽¹⁵⁾ and converted to Thai's utility score⁽¹⁶⁾. SSI usually occurred within one week, but it could be anytime within 30 days after the operation, and it would take one to two weeks of wound care and antibiotics. Thus, utility at day 30 was used to represent the overall health state in the present model. A utility score of 1 represented full health, whereas 0 represented death. Again, utility scores were obtained separately for SSI and non-SSI patients (0.977 and 0.995, respectively). These scores were multiplied by 30 to adjust for further QALD calculation.

Cost-utility analysis

Costs and utilities of SSI and non-SSI patients from the previous study were inputted into the model and multiplied with probabilities of the event for SSI or no SSI, to obtain costs and QALDs of each path of the model. Then, costs and QALDs of the two treatment options as RWP and no RWP, were calculated from the summation of the costs and the QALDs of both SSI and non-SSI regarding each treatment. Deterministic incremental cost-effectiveness ratio (ICER) was calculated by dividing Δ cost with Δ QALD, where Δ cost and Δ QALD were the difference of costs and QALDs between appendectomy with and without RWP. In the other words, ICER could be written in

Table 1. Mean and standard error of input parameters

Parameter	Distribution	Mean	SE
Total cost			
SSI	Gamma	9,282.81	1,507.07
No SSI	Gamma	5,936.48	180.75
Utility			
SSI	Beta	0.977	0.007
No SSI	Beta	0.995	0.001
Probability of SSI			
RWP	Beta	0.039	0.009
No RWP	Beta	0.117	0.015

RWP=ring wound protector; SE=standard error; SSI=surgical site infection

the equation as follows:

ICER = $\Delta cost/\Delta QALD$

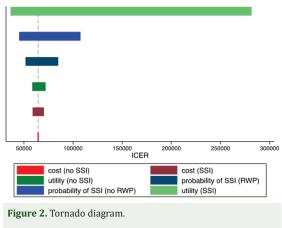
ICER represents the incremental cost to gain one additional QALD.

One-way sensitivity analysis

Costs, utilities, and probabilities of SSI were varied one at a time within their 95% confidence intervals (CI). Then, the range of possible ICER was calculated and presented in a tornado diagram. Threshold analyses were also performed to find the appropriate RWP cost to be cost-effective regarding each willingness-to-pay (WTP) threshold, which was arbitrarily set as 500, 1,000, and 10,000 THB/QALD. Because the benefit in the present study was reported as a QALD to be in line with a 30-day time horizon, using the Gross Domestic Product (GDP) per capita as a WTP threshold would not be appropriated.

Probabilistic sensitivity analysis

Monte-Carlo simulation was performed to generate 5,000 replications of costs and utilities of SSI and non-SSI group, and probabilities of SSI in RWP and no RWP patients, by using input parameters and distribution shown in Table 1. Then, $\Delta costs$ and Δ QALDs were calculated from each replication. Coordinates of \triangle cost and \triangle QALD were plotted on a cost-effectiveness plane, representing $\Delta QALD$ and $\Delta cost$ on the x-axis and y-axis. The area in the right lower quadrant favored RWP use, whereas the left upper quadrant favored no RWP. WTP lines were drawn on the same plane. Cost-effectiveness would be indicated if coordinates fell below the WTP line. The chance of being cost-effective (i.e., the proportion of coordinates that fell below the WTP threshold to all coordinates) was plotted against the WTP threshold on an acceptability curve, assigning WTPs on the



ICER=incremental cost-effectiveness ratio; RWP=ring wound protector; SSI=surgical site infection

x-axis and the probability of being cost-effective on the y-axis. In addition, ICERs were calculated from each pair of Δ cost and Δ QALD. By averaging these ICERs, a single probabilistic ICER with 95% CI was obtained.

Additional sensitivity analysis

The utilities at three days after appendectomy were used to represent the overall health state in the model. The utilities were 0.850 and 0.887 for SSI and non-SSI patients, respectively. Deterministic and probabilistic ICERs were re-calculated. Furthermore, the cost-effectiveness plane and acceptability curve were reconstructed. Stata Statistical Software, version 17 (StataCorp LLC, College Station, TX, USA) was the software used in all analyses.

Results

Appendectomy with and without using RWP yielded QALDs of 29.82 and 29.78 days, respectively. The total cost of treatment was 8,916.99 THB in the RWP group and 6,328 THB, in the no RWP group. As a result, the deterministic ICER of RWP use was 64,630.78 THB/QALD, which was far from being cost-effective compared with the WTP thresholds of 500, 1,000, and 10,000 THB/QALD.

One-way sensitivity analysis

When each input parameter was varied one at a time, the deterministic ICER was changed as demonstrated in the tornado diagram (Figure 2). Costs of treatment, both in the SSI and non-SSI group, had only a slight effect on the ICER. However, the ICER would be changed if the utility of SSI patients was varied. By performing threshold analysis, RWP should

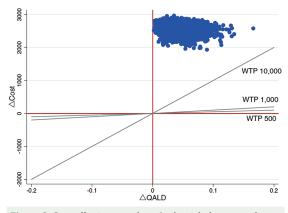


Figure 3. Cost-effectiveness plane. In the right lower quadrant, ring wound protector (RWP) is superior to no RWP. In the left upper quadrant, no RWP is superior to RWP.

QALD=quality-adjusted life day; WTP=willingness-to-pay

cost 281, 301, and 661 THB to be cost-effective at the threshold of 500, 1,000, and 10,000 THB/QALD, respectively.

Probabilistic sensitivity analysis

The probabilistic ICER was 83,309.82 THB/ QALD (95% CI 81,714.11 to 84,905.52). As shown in Figure 3, none of the coordinates between Δ costs and Δ QALDs fell below any reference WTP threshold. This finding had confirmed the deterministic analysis that using RWP was not cost-effective considering QALD as an outcome. When the WTP threshold was varied, the probability of being cost-effective would be 24.4% if the WTP threshold was 50,000 THB/ QALD. This probability became 75.3% at the WTP threshold of 100,000 THB/QALD, Figure 4a.

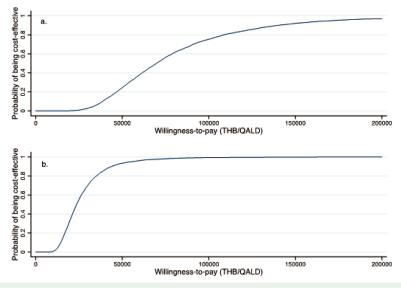
Additional sensitivity analysis

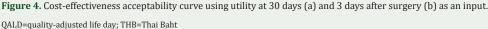
When utilities at three days instead of thirty days after surgery were used, the deterministic ICER was 29,541.18 THB/QALD. The probabilistic ICER was 27,919.02 THB/QALD (95% CI 26,819.99 to 29,018.04). The probability of being cost-effective was 0.8% and 93.4% at the WTP thresholds of 10,000 and 50,000 THB/QALD, respectively (Figure 4b).

Discussion

Even though studies indicated wound protector's clinical effectiveness⁽⁶⁻¹¹⁾, the present study did not demonstrate the cost-effectiveness of routine RWP use in open appendectomy. Both deterministic and probabilistic ICERs were very high compared with the WTP thresholds set at 500, 1,000, and 10,000 THB/QALD. The acceptability curve demonstrated that RWP could be cost-effective at the higher WTP threshold. This finding suggested that RWP should be used in selected patients whose sick leave will associate with societal loss.

Results from the threshold analysis suggested that RWP's cost must be 281 to 661 THB to be cost-effective at the reference thresholds of 500 and 10,000 THB/QALD. Re-sterilization and repeat use of the device might be another way to improve costeffectiveness. Even though the device is designed as





single-use equipment, re-use is common in developing countries.

The strength of the present study is that SSI probabilities were obtained from the meta-analysis⁽¹¹⁾, in which 92.8% of pooled patients were classified as having contaminated or dirty surgical wounds. Moreover, utilities and costs were retrieved from the large randomized clinical trial⁽¹⁴⁾ in Thailand. That clinical trial also targeted complicated appendicitis. Therefore, using input parameters from these studies in the present analysis should reflect the cost-effectiveness in the complicated appendicitis patient who should benefit from SSI prevention.

The present study is one of only few economic evaluations of wound protectors. None of the studies has ever assessed RWP cost-effectiveness in open appendectomies. Based on the results from the present study, policy-makers could be informed that the adoption of this health technology in routine practice might not be suitable.

However, some limitations have been acknowledged. This decision tree model assumed all patients recovered without long-term consequences whether SSI occurred or not. This model also assumed that only two events could occur following appendectomy as SSI or no SSI. Patients might experience rare events, such as enterocutaneous fistula, intra-abdominal collection, or organ injury. These rare complications will increase overall treatment cost and lower patient utility. However, due to their rarity, they should not significantly affect the accuracy of the model. Moreover, these complications were not affected by RWP use. The probability of SSI was obtained from the meta-analysis that included foreign studies that might not represent SSI risk in Thailand.

The utility assessed at 30 days after the operation, which was used as input in the model, might not accurately reflect actual utility during recovery. An observed slight difference in QALD between SSI and non-SSI patients might be caused by this limitation, which made ICER higher and RWP not cost-effective. However, the sensitivity analysis using utilities three days after the operation, in which a more considerable QALD difference could be observed, did not demonstrate the cost-effectiveness of this device.

Conclusion

Routine RWP use might not be cost-effective when QALD is the outcome of interest. Further study should prospectively collect all parameter data to improve the accuracy. However, further study might not change the conclusion based on the low probability of being cost-effective observed in the present study.

What is already known on this topic?

Studies have confirmed the clinical effectiveness of RWP in abdominal operation. One meta-analysis indicated RWP's effectiveness in open appendectomy.

What this study adds?

Few cost-effectiveness studies have been conducted to assess RWP use and there is no study in appendectomy incision, one of the most common abdominal operations. This study identified that RWP was not cost-effective when the outcome was the quality of life.

Authors' contribution

Sukhvibul P performed model construction and data analyses. The manuscript was drafted by Techapongsatorn S, and revised by Tansawet A. Siribumrungwong B provided data from his study for model input. Chaiyakittisopon K and Tansawet A supervised this study. All authors have approved this manuscript.

Conflict of interest

All authors declare no conflict of interest.

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