Outcomes and Cost Minimization between Siriraj Cold Hot Pack and the Innovator Product

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ABSTRACT

Objective: To evaluate the quality of product and compare outcomes and costs between Siriraj Cold Hot Pack and an innovator product from the patient and hospital perspective.

Methods: Siriraj Cold Hot Packs were prepared and tested for outcome and cost with the innovator product. The criteria for comparison such as heat and cold retention, compression resistance and skin irritation between the Siriraj Cold Hot Pack and the innovator product were determined and then analyzed for the economic effect by cost minimization analysis.

Results: Siriraj Cold Hot Pack exhibited standard characteristics ($p > 0.05$). After being soaked in 95-100°C for 5 minutes or in 70-80°C for 7 minutes, it could retain heat at a temperature higher than 43°C for at least 10 minutes. It also retained cold at temperature below 10°C for longer than 10 minutes after being stored in a freezer for 2 hours, in a refrigerator (2-4°C) for 4 hours or on ice for 20 minutes. The comparison of heat and cold retaining and compression resistance between the Siriraj Cold Hot Pack and the innovator product revealed no difference. However, when they were soaked with water and heated with a microwave at 600 watts for 2 minutes, the Siriraj Cold Hot Pack was able to significantly retain heat longer than the innovator product ($p < 0.05$). For economic analysis, Siriraj Cold Hot Pack is the best choice. The sensitivity analysis from the patient perspective was conducted by increasing the price of the Siriraj Cold Hot Pack until greater than 25%, both products will be equivalent the best choice. From the hospital perspective, increasing the cost of production until greater than 102%, both products will be equivalent the best choice.

Conclusion: The results show that Siriraj Cold Hot Pack yielded the similar capability to the innovator product, including hot and cold retention, compression resistance and the irritation results. Siriraj Cold Hot Pack is the best choice for both the patient and hospital perspective.

Keywords: Cost minimization, hot and cold retention, compression resistance

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Hot therapy induces vasodilation which results from relaxation of smooth muscle cells within the vessel walls by drawing blood into the target tissues. Increased blood flow delivers needed oxygen and nutrients, and removes cell wastes. The warmth when heat therapy relaxes tense muscles, decreases muscle spasm, relieves pain, and can increase the range of motion while cold therapy (Cryotherapy) produces vasoconstriction, which slows circulation reducing inflammation, pain, and muscle spasm. Edema resulting from trauma is increased with heat, and decreased in its development by cold application. Joint stiffness is decreased with heat application and increased with cold application.[1] Physiological studies indicated cold therapy resulted in vasoconstriction, reduction of edema, and diminished pain perception. Various methods can be used to lower tissue temperature. Ice or gel packs are easy and efficient techniques to cool tissues. The contrast therapy has little effect on deep muscle temperature. Therefore, if most of the physiologic effects attributed to cold and hot contrast therapy depend on substantial fluctuations in tissue temperature, contrast therapy needs to be reconsidered as a viable therapeutic modality.[2]

Superficial heat and cold is available in many forms, including hot and moist compresses, dry or moist

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heating pads, hydrotherapy, cold packs, ice cubes, and forms of hydrotherapy. The duration of cold therapy is less than heat therapy; usually less than 15 minutes. The effect of cold is known to last longer than heat.[3]

In drug stores, many cold hot packs were available but they have the difference of cost and some capability such as the gel change to the ice and discomfort feeling as when we use the ice on the skin it leads to the lower comfortable feeling, but cheaper than another brand such as the innovator product. For this reasons, our institution investigated the gel of cold and hot therapy for our patient which is the similar property and cheaper than the innovator product and analyzed the outcomes and costs. This study was performed from the hospital and patient perspective.

Expiration date after use for hot and cold therapy is 6 months.[4] Level of the temperature that is appropriate for the hot therapy is 43-45°C, between 20 to 30 minutes. If the temperature was higher than this range, the tissue was damaged. Cold therapy usually decreased skin temperature to 10-15°C within 10 to 20 minutes or 0-10°C, less than 15 minutes.[4,5] Hot packs in any form should always be wrapped in a towel to prevent burns. Punctured commercial hot packs should be immediately discarded, as the chemical agent such as gel may burn skin as well as cold packs should never be applied directly to the skin. A towel should be placed between the cold packs and the skin's surface to prevent skin and nerve damage. Punctured commercial cold packs should be immediately discarded, as the chemical gel may burn skin[1,4,5] though the composition of the Siriraj Cold Hot Pack is the chemicals which are usually used in cosmetic products and safe for skin contact.[6]

MATERIALS AND METHODS

1. Instrumentation

- Universal Testing Maching Instron Model4206
- Digital thermometer
- Microwave
- Refrigerator
- Boiling and hot water
- Ice and cold water
- Towel
- Cold Hot Pack (the equivalent size): Siriraj Cold Hot Pack, Innovator product 5 pieces per 3 batches per time of evaluation the same as the criteria for evaluation of pharmaceutical products.[7-9]

2. Product qualification by Department of Science Service, Ministry of Science and Technology to avoid the bias. The methods consist of the following

Cold retention

Measuring the time that it could retain cold at a temperature below 10°C for at least 10 min after being stored in a freezer for 2 hours, refrigerator for 4 hours, or placed in ice water for 20 minutes.

Hot retention

Measuring the time that it could retain heat at a temperature higher than 43°C for at least 10 min. after being immersed in boiling water at a temperature of 95-100°C for 5 minutes, immersed in boiling water at a temperature 70-80°C for 7 minutes, placed in a plastic container, or soaked with 1,000 ml. of water and heated with a microwave at 600 watts for 2 minutes.

Compression resistance

The results of compression, tested by a universal testing machine Instron Model : 4206 with crosshead rate 10 mm/min at a temperature of 26 ± 2°C. The result was kilogram-force of the product to resist the compression.

Irritation test

Irritation test was performed by placing the sample pack on various parts of the body: forehead, cheek, nape, lower abdomen, spine and inner part of the arm. The testing time was one hour, and then observe if there was any sign of skin allergy.

3. Statistical analysis: Comparisons between 3 batches of both products were considered statistically significant with ANOVA test and independent t-test to compare the difference between 2 products when the p-value was 0.05 or less. Statistical software (SPSS version 13.0), was used for all calculations.

4. Outcomes and cost analysis

Outcomes included the duration time of hot and cold retention and the compression resistance of both products, the duration of cold and hot retaining time when used for physical therapy, and the product acquisition cost.

Cost-minimization analysis was performed when the qualification of product has a similar result. We conducted a cost-minimization analysis by estimating the product cost associated with pain relief, from the perspective of patient and hospital. One way sensitivity analysis was performed for the uncertainty of production cost by increasing the price or decreasing the cost of the Siriraj product.

RESULTS

The formulation of the Siriraj Cold Hot Pack were prepared for 3 batches which comprise either water or a gel material contained in a flexible and liquid impermeable membrane plastic which was heated and cooled under criteria conditions so they can become warm and cool to touch within the acceptable time. All batches were not statistically significant different ($p > 0.05$, ANOVA). The qualification of the Cold Hot Pack device results are shown as follows:

Cold retention

Both products were not statistically significantly different in cold retention as shown in Table 1.

TABLE 1. The results of average time for cold retention.

Cold retention	Sample	Mean (min)	SD.	p-value
Freezer for 2 hours	Siriraj Cold Hot Pack	92.4	13.0	0.945
	Innovator product	93.0	13.5	
Refrigerator for 4 hours	Siriraj Cold Hot Pack	45.0	14.78	0.104
	Innovator product	29.3	8.73	
Placed in ice water for 20 minutes	Siriraj Cold Hot Pack	14.3	6.85	0.258
	Innovator product	21.4	9.79	

TABLE 2. The results of the average time for heat retention, when they were immersed in boiling water at temperature 95-100°C for 5 minutes.

Hot retention	Sample	Mean (min)	SD.	p-value
Immersed in boiling water at temperature 95-100°C for 5 minutes	Siriraj Cold Hot Pack	119.60	17.13	0.321
	Innovator product	130.80	16.33	
Immersed in boiling water at temperature 70-80°C for 7 minutes	Siriraj Cold Hot Pack	101.40	22.63	0.852
	Innovator product	99.20	11.10	
Placed in plastic container, soaked with 1000 ml. of water and heated with a microwave at 600 watt for 2 minutes	Siriraj Cold Hot Pack	40.5	2.347	0.008
	Innovator product	36.6	0.950	

Hot retention

Both products were not statistically significantly different in heat retention as shown in Table 2.

Compression resistance

Both products were not statistically significant different in compression resistance as shown in Table 3.

TABLE 3. The results of compression, tested by universal testing machine Instron Model: 4206 with crosshead rate 10 mm/min at temperature 26 ± 2°C.

Sample	Mean (kgf)	SD.	p-value
Siriraj Cold Hot Pack	1,002.60	91.336	0.330
Innovator product	1,058.00	58.270	

kgf : kilogram-force

Irritation test

The results of the irritation test (the sample pack on was placed on various parts of the body: forehead, cheek, nape, lower abdomen, spine and inner part of the arm, with a testing time of one hour, then observe if there was any sign of skin allergy) are shown in Table 4.

Economic analysis

Although the heat retention of both products were different when placed in a plastic container, soaked with 1,000 ml. of water and heated with a microwave at 600 watts for 2 minutes, but other conditions for heat retention were not different as shown in the Table 2, so we summarized that outcomes of the products such as cold retention, heat retention, compression resistance, and irritation property were not statistically significantly different, so both products had similar outcomes. Thus cost minimizations were performed. Cost analysis includes only the product cost because other costs such as physician and nurse care cost, cost of procurement and management of product stock is equal. From the patient perspective this includes the price of the product that the patient has to pay out of their own pocket while the hospital perspective includes the cost of the product that the hospital pays for the product procurement, production and management. The result of product quantification has shown that the outcomes are similar so that we used cost minimization for economic analysis, lowest cost alternative is the best choice for both perspectives. As shown in Table 5, the Siriraj Cold Hot Pack is the best choice.

TABLE 5. Cost in the patient and hospital perspective.

Sample	Cost/time (patient perspective)	Cost/time (hospital perspective)
Siriraj Cold Hot Pack	95.00	48.20
Innovator product	118.00	97.00

One-way sensitivity analysis

For the patient perspective, the Siriraj Cold Hot Pack dominated the innovator product until the product cost of the Siriraj Cold Hot Pack increased by 25% from 95 Baht/piece to 118.8 Baht/piece, when the price of the innovator product was fixed at 118 Baht (Fig 1).

For the hospital perspective, the Siriraj Cold Hot Pack dominated the innovator product until the product cost of the Siriraj Cold Hot Pack increased by 102% from 48.2 Baht/piece to 97.36 Baht/piece, when the price of the innovator was fixed at 97 Baht (Fig 2).

DISCUSSION

The formulation of the Siriraj Cold Hot Pack were prepared for 3 batches which comprise either water or a gel material contained in a flexible and liquid impermeable membrane plastic which was heated and cooled under criteria conditions that can store heat and cold within the acceptable time. All batches were not statistically significant different ($p > 0.05$, ANOVA).

To test for heat retention, the Siriraj Cold Hot Pack and the innovator product were placed in boiled water (95-100°C) for 5 minutes, or hot water (70-80°C) for 7 minutes, so they can store heat to touch not less than 43°C within the acceptable time (more than 10 minutes). About cold retention, the test was performed by conditions such as specified temperature and time, such as a household freezer for 2 hours, refrigerator 4-6°C for 4 hours and ice for 20 minutes, so they can store cold to touch not more than 10°C within the acceptable time (more than 10 minutes). The average time of both products was not statistically significant

TABLE 4. The results of irritation test, tested by placing the sample pack on various part of the body, then observe if there is any sign of skin allergy.

Sample	No.1	No.2	No.3	No.4	No.5	Average
Siriraj Cold Hot Pack	Not to irritate	Not to irritate	Not to irritate	Not to irritate	Not to irritate	Not to irritate
Innovator product	Not to irritate	Not to irritate	Not to irritate	Not to irritate	Not to irritate	Not to irritate

Based on the results from Table 4, all products were non-irritant.

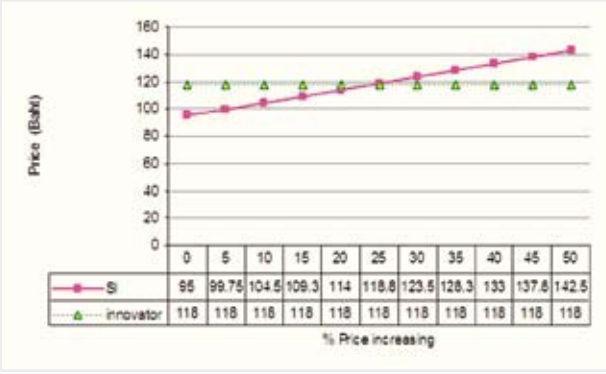

Fig 1. One-way sensitivity analysis of % price increasing.

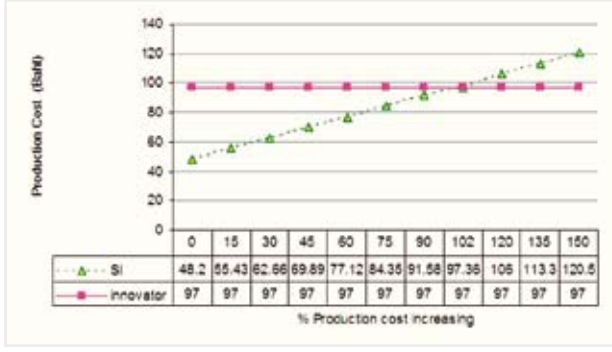

Fig 2. One-way sensitivity analysis of % production cost increasing.

different in heat and cold retention ($p > 0.05$, Independent-samples t-test). The compression was tested by the Universal testing Machine Instron Model: 4206 with crosshead rate 10 mm/min at the temperature 26 ± 2°C. The average compressive force of both products was not statistically significantly different ($p > 0.05$, Independent-samples t-test). However, when they were placed in a plastic container and filled with 1,000 ml., of water over them, then heated in a microwave oven 600 watts for 2 minutes, the Siriraj Cold Hot Pack can store heat to touch more than the innovator product so there were statistically significant differences ($p < 0.05$, Independent-samples t-test). About irritation to skin, both products did not irritate.

Although the heat retention of both products were different when placed in a plastic container, soaked with 1,000 ml. of water and heated with a microwave at 600 watts for 2 minutes, other conditions for heat retention were not different as shown in the Table 2 so that we summarized that the outcomes of the products were cold, heat retention, compression resistance, and irritation property which were not significantly different which means both product were similar thus cost minimizations were performed, and the lowest cost alternative is the best choice for both perspectives and the results show that the Siriraj Cold Hot Pack is the best choice. The sensitivity analysis in the patient perspective was conducted by considering if the price of the Siriraj Cold Hot Pack increased greater than 25%, both products will be equivalent best choices. From the hospital perspective, if the production cost was greater by 102%, both products will be equivalent best choices.

CONCLUSION

The results show that the Siriraj Cold Hot Pack yielded the similar capability to the innovator product, including heat and cold retention, compression resistance and the irritation results. Nevertheless, the Siriraj Cold Hot Pack decreased the total costs to the resolution of pain treatment by hot and cold therapy. For economic analysis, the Siriraj Cold Hot Pack is the best choice. The sensitivity analysis in the patient perspective was conducted by considering if the price of the Siriraj Cold Hot Pack increased greater than 25%, both products would be equivalent best choices. For the hospital perspective, if the production cost was greater than 102%, both products will be equivalent best choices.

The limitation was that we evaluated only product acquisition costs when we determined the economic effect of implementing the product. However, additional factors, such as product formulation and preparation and administration costs, also contributed to the overall costs of treating a patient. Additional costs such as those related to nursing administration time and labor are generally considered fixed costs that would not have been affected.

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REFERENCES

1. Preisinger E, Quittan M. Thermo- and hydrotherapy. Wien Med Wochenschr 1994;144(20-21):520-6.
2. Myrer JW, Measom G, Durrant E, Fellingham GW. Cold- and hot-pack contrast therapy: subcutaneous and intramuscular temperature change. J Athl Train. 1997 Jul;32(3):238-41.
3. Lehmann JF, Warren CG, Scham SM. Therapeutic heat and cold. Clin Orthop Relat Res. 1974 Mar-Apr;(99):207-45.
4. Thitisattayakorn S. Hot and cold therapy devices MDCiT, Bangkok; 2006. p. 1-26.
5. Greenstein G. Therapeutic efficacy of cold therapy after intraoral surgical procedures: a literature review. J Periodontol. 2007 May;78(5):790-800.
6. HK A. Handbook of Pharmaceutical Excipients: American Pharmaceutical Association; 2000. p. 79-90.
7. Prakongpan S. Stability of medicine. Pharmaceutics Department, Mahidol University, Bangkok, 1997. p. 120-37.
8. Janthrasakul J, Rakvathin J, Sarisut N, Prakongpan S, Pithayanukul P. Stability test of Medicine. Thai Drug Analysis Devision, 1992. p. 410.
9. Janyaprasert W. Solution dosage form and pharmaceutical product stability, Bangkok, 1997. p. 60-63.