

Development of a RAMA Gallbladder Retrieval Bag for Improved Patient Safety: A Nursing Innovation

Peinjit Bhumisirikul, Natthacha Chiannilkulchai*

Abstract: One of the major problems in laparoscopic cholecystectomy is the bile and stone spillage into the abdominal cavity, which results in contamination. Thus a retrieval bag is used to prevent this problem. This study aims to describe the further development of an existing retrieval bag for improved patient safety and the evaluation of the effectiveness of the new version of RAMA retrieval bag. The study was conducted in two phases: design and development of the new retrieval bag and evaluation of its efficacy. For the efficacy evaluation, data regarding problems in using the retrieval bag were collected from surgeons on 110 laparoscopic cholecystectomy procedures from January to April 2017, and the surgeons' opinions regarding use of the retrieval bag. Descriptive statistics were used to analyze the data.

The results showed that after the surgical procedure was completed for all patients, no problems occurred during gallbladder removal and no bags were broken. Bag closure was somewhat difficult in three cases (2.7%). According to the 12 surgeons' opinions, the overall effectiveness of RAMA retrieval bag was highly rated with both high safety and function. The redesigned retrieval bag is easy to open and prevent the specimen leaving from the bag, resulting in patient safety. The cost of the new version is much less than the cost of other retrieval bags. This bag is convenient and require less time for the nurses in preparation instruments during surgery.

Pacific Rim Int J Nurs Res 2018; 22(3) 264-277

Keywords: Equipment design, Gallbladder, Laparoscopic cholecystectomy, Medical device, Patient safety, RAMA retrieval bag

Received 16 November 2017; Accepted 1 March 2018

Introduction

Laparoscopic cholecystectomy (LC) is currently one of the most commonly performed surgical procedures to remove the gallbladder because of its small incision, minimal pain, and short hospital stay.¹⁻³ One of the major steps in LC is extraction of the gallbladder from the abdominal cavity to prevent bile and stone spillage into the abdominal cavity resulting in the formation of adhesions, abdominal abscesses, and peritoneal cystic masses.^{4, 5} A retrieval bag is used to prevent bile and stones spillage

Peinjit Bhumisirikul, RN, MNS (administration) Division of Perioperative Nursing, Department of Nursing, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand

Correspondence to: Natthacha Chiannilkulchai, RN, PhD. Assistant Professor, Ramathibodi School of Nursing, Faculty of Medicine Ramathibodi Hospital, Mahidol University, 270 Rama 6 Road, Phayathai, Rachathewi, Bangkok 10400, Thailand. E-mail: natthacha.chi@mahidol.ac.th*

from a gallbladder rupture during removal of the gallbladder from the abdominal cavity in LC.¹⁻³ Before 2000, most surgeons in our hospital did not use a retrieval bag to enclose the gallbladder before extracting it from the abdominal cavity because most of the commercial

retrieval bags are expensive, and vary in their advantages and limitations.^{3, 6, 7} Suitable medical devices may vary in design among different communities. Some medical institutes produce medical devices, especially gallbladder retrieval bags, for their own use.^{8, 9} This is because user requirements are sometimes locally driven and generally embedded in the socioeconomic status of the users.¹⁰

Bile and stone spillage into the abdominal cavity, which can be harmful to patients, is a matter of concern to perioperative nurses who work and collaborate with surgeons to advocate patients' safety. Speaking on behalf of patients is essential in the operating room, where patients are defenseless after sedation or anesthesia.¹¹ Patient advocacy is a responsibility of all nurses at all times.¹¹ Therefore, our hospital has been using homemade retrieval bags developed by the first author and her team to prevent potential harm related to bile and stone spillage into the

abdominal cavity and reduce the cost of laparoscopic surgery.¹²

The first version of the retrieval bag had a cone shape with an opening system for insertion of an instrument into a 10 mm. port (**Figure 1**).¹² However, with the further development of laparoscopic surgery, surgeons changed the size of the epigastrium port from 10 mm. (which was the port used to remove the gallbladder bag) to a 5 mm. port. The procedure used to remove the retrieval bag should be changed from the epigastrium port to the umbilical port (which was used for an endoscope). In the first version, the endoscope must be inserted in the umbilical port and the retrieval bag must be inserted and removed in the epigastrium port because the bag cannot be inserted together with the endoscope in the umbilical port. In the new version, the bag must be removed from the umbilical port, so the bag design needed to be changed.



Figure 1 The first version of retrieval bag

Therefore, the second version was designed and developed, using a tying thread instead of an opening system, which was suitable for use with an endoscope in the umbilical port. The second version was distributed and widely used in many hospitals in Thailand (**Figure 2**).¹³ However, the second version of our retrieval bag also had problems with use. Keeping the open-end of the retrieval bag open was somewhat difficult because of its design. The bag also had less flexibility, which caused bag breakage when force was used to remove the bag through the

port site, because the material used was a food-grade plastic. Additionally, the shape of the second version was cylindrical, and the open-end and the bottom sections were symmetrical. After placing the gallbladder in the retrieval bag, the longest part of the gallbladder was sometimes located horizontal to the port site, which obstructed removal. If extraction of the gallbladder from the abdominal cavity through the port incision was difficult, the surgeon might extend the port incision or use force to retract the gallbladder through the port incision. This surgical step may cause tissue trauma

around the port site.^{14, 15} Thus, a poor device design can impact patient safety.^{16, 17} For better patient safety and to reduce adverse events associated with

use of the earlier version of the retrieval bag, a new version of the retrieval bag was developed and named RAMA retrieval bag.



Figure 2 The second version of retrieval bag

Conceptual Framework and Literature Review

In developing countries, especially Thailand, nurses should be involved in the development of various kinds of medical devices for use in their hospitals instead of using commercial medical devices which are more expensive. Some nurses are engaged in device development and evaluate the usability of their devices and convey awareness from a patient's viewpoint.¹⁸ Although there are numerous published papers on nurses involved in medical device development, there is limited direction on how to include nurses in the early steps of medical development teamwork.^{18, 19} To describe our role as nurses in medical device development in this study, the conceptual framework was derived and refined from several concepts on the role of nurses in medical device development, hazards with medical devices, and promotion of the safe use of medical devices.^{18, 20, 21} The device development process of this study started with identifying the needs and requirements for developing

a new version of the retrieval bag which was redesigned for preventing adverse events, ease of use, and low cost. This sequential process included design and testing phases to evaluate the effectiveness/ performance of an improved medical device. The device design was based upon user requirements.²² The user requirements in this study were the surgeons' requirements, which meant that the retrieval bag should be easy to open and more flexible. Testing of a medical device or evaluation of its effectiveness include technical functions and other indicators, such as ease of use and clinical acceptability.²³ In the present study, the authors recorded problems in using the retrieval bag to evaluate device design and the surgeons' opinions to evaluate retrieval bag functions and clinical acceptability. The bag described in this study was proposed as an improved design for increased patient safety and was evaluated in terms of clinical effectiveness.

Purpose of the Study

The overall objective of this study was to further develop the existing retrieval bag with respect to

improved patient safety and evaluate the effectiveness of the new version of RAMA retrieval bag for extraction of the gallbladder from the abdominal cavity during laparoscopic surgery.

Methods

Study design

Design and development research was conducted to develop the new version of the retrieval bag. This study design consisted of the systematic design, development and evaluation processes in order to establish an empirical basis for the creation of instructional and non-instructional products and tools and new or enhanced models that govern their development.²⁴ This approach is usually used to guide the development of new products and tools. The present study was conducted in two phases: design and development of RAMA retrieval bag and evaluation of its efficacy. The details of each phase are as follows.

1. Design and development

Reported problems and user requirements were assessed to define design criteria that are appropriate

within the clinical setting.¹⁰ The design criteria of the new retrieval bag included two conditions: a cone shape that was easy to open and a simple design that prevented the opposite side from collapsing. Accordingly, a medical-grade plastic sheet was used to produce the retrieval bag with a 21 cm. long upper section and a 12 cm. long bottom section. The height from the bottom section to the upper section was 16.5 cm. The upper section was folded and sealed along a horizontal line by placing a 60 cm. long no.1 silk thread inside. This upper section became the open portion that served as the specimen receptacle. Next, this plastic sheet was symmetrically folded along a vertical line, and the seal mark was reversed so that it was on the inside. The bottom and lateral sections were then sealed 0.5 cm. away from each side (**Figure 3**). A knot was designed to tie the upper section and thus formed a closing system. The two ends of the thread were overlapped, with the end of the left part above the right part. The right part was held upward above the left part and inserted through the loop. Next, the end of the right part was turned upward on the left part and inserted into the loop to create a tied



Figure 3 Folding and sealing the plastic sheet along a vertical line.

knot (**Figure 4**). After creating the knot, this new version was 10 cm. wide at the upper section, 5.5 cm. wide at the bottom section, and 15 cm. high from the bottom to upper sections. In preparation for sterilization, the lateral side was rotated to the median side, and the

bottom part was folded inside and upward. The height of the anterior part was then 1 cm. lower than the posterior part, resulting in a concave shape. The knot was placed in the posterior part, making the bag easy to close (**Figure 5**).

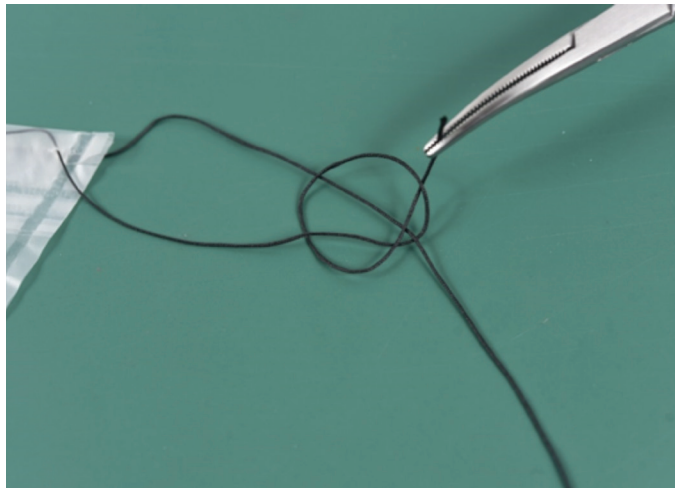


Figure 4 The right part was held backward upon the left part and inserted through the loop to create a tied knot.



Figure 5 The retrieval bag before pilot test used no. 1 silk tread for tying.

To initially evaluate the design function and improve the design pattern of RAMA retrieval bag, a pilot test was conducted with three surgeons. After they used RAMA retrieval bag, one of the surgeons

stated that the silk thread was not smooth, making it difficult to swipe. Because difficulty in usability can contribute to incidents of serious harm,²¹ the no. 1 silk thread was changed to no.1 nylon thread (**Figure 6**).



Figure 6 The retrieval bag after the pilot test uses no. 1 nylon thread for tying.

This new retrieval bag is made of medical-grade plastic. The bag is cone-shaped, and the length of the bottom section is shorter than the open-end section. This feature of RAMA retrieval bag positions the gallbladder vertically and allows it to be easily removed from the abdominal cavity. The concave shape at the open end which makes it easier to open when surgeons placed the gallbladder inside the bag and the nylon thread was tightly closed.

The price of RAMA retrieval bag is 400 baht (12.12 USD). Some hospitals in Thailand have been using imported gallbladder retrieval bags whose price range was from 800 – 1000 baht (24.24 – 30.22 USD). Also the commercial bags do not have the same advantages. For example, commercial bags do not have a concave shape and do not use typing thread to close the bag.

2. Efficacy evaluation

Evaluation of the effectiveness of the retrieval bag with respect to patient safety included assessment of the problems in using the retrieval bag for patients who underwent LC from surgeons and the opinions of the surgeons regarding use of RAMA retrieval bag.

Instruments

A record of the problems in using RAMA retrieval bag was kept by the authors to test the structural design

of RAMA retrieval bag in terms of whether it functions properly. This record consisted of six factors: cases of bile leakage or stone spillage from RAMA retrieval bag into the abdominal cavity, bag opening problems, bag breakages, tearing of tying material upon bag closure, difficulty in closing the bag, and obstruction of the bag at the port site.

The retrieval bag evaluation form was based on the surgeons' opinions regarding use of RAMA retrieval bag which were used to evaluate the effectiveness of RAMA retrieval bag. Specific characteristics of the bag structure were identified, and items useful for assessment of the effectiveness of RAMA retrieval bag were composed. The evaluation instrument contained 12 items grouped into 3 main subscales: functions of the retrieval bag, usability of the retrieval bag, and safety of using the retrieval bag to ensure that use of the bag results in increased patient safety in practice.¹⁷ A five-point Likert scale was used, ranging from 1 (very ineffective) to 5 (very effective); higher scores were associated with greater effectiveness. The instrument's content validity was determined by a panel of three experts, who stated that the content validity index of the 12 items was 0.97. One item without clear content was discarded. Thus, 11 items were used to examine the internal consistency reliability (Cronbach's alpha

coefficient), based on 3 pilot surgeons' opinions and the alpha coefficient was computed to be 0.96. The overall Cronbach's alpha coefficient of the instrument after assessment by all 12 participating surgeons was 0.93; the grouped items showed a coefficient of 0.82 for the function subscale, 0.85 for the usability subscale, and 0.94 for the safety subscale. For example the function subscale composed of 3 items: the retrieval bag is located in the vertical position, prevention of gallstone spillage from the gallbladder sac, and prevention of abdominal cavity contamination. The intercorrelation of these 3 items was 0.82.

Sample and setting

The sample contained of 2 groups: surgeons who used RAMA retrieval bag in laparoscopic surgery and patients who were diagnosed with gallstones. These surgeons were selected by purposive sampling based on all surgeons who practiced at the studied hospital. All surgeons with more than 3 years of experience in LC and who had used RAMA retrieval bag with more than three patients were included. Surgeons with experience in LC less than 3 years were excluded. In total, 15 prospective surgeons were identified. Of these, 12 surgeons met the inclusion criteria and stated their willingness to participate in this study.

Patients who had gallstones and underwent LC were included. Patients who had a gallbladder polyp,

and emergency cases, were excluded. In total, 135 prospective patients were identified. Of these, 110 patients met the inclusion criteria.

Ethical considerations

This study was approved by the Research Ethics Committee of Ramathibodi Hospital, Mahidol University, with which the authors are affiliated (IRB no. MURA 2016/661). Each surgeon received information including the purpose of the study, data collection, potential withdrawal decision, and confidentiality of participation in the study to ensure their privacy. Problems in using the retrieval bag on 110 patients were provided by surgeons without patient identification. All collected information was discarded after completion of the study.

Data collection

After the research project was approved by the Research Ethics Committee of Ramathibodi Hospital, Mahidol University. The 12 participating surgeons provided written informed consent when using RAMA retrieval bag at least three times. Then, they were asked to complete the questionnaire for evaluation RAMA retrieval bag. Data were collected from January to April 2017. All patients underwent standard four-port LC with one 10-mm. umbilical port and three 5-mm. ports (one in the epigastrium and the other two on the right side). After RAMA retrieval bag was inserted into the abdominal cavity (**Figure 7**), the

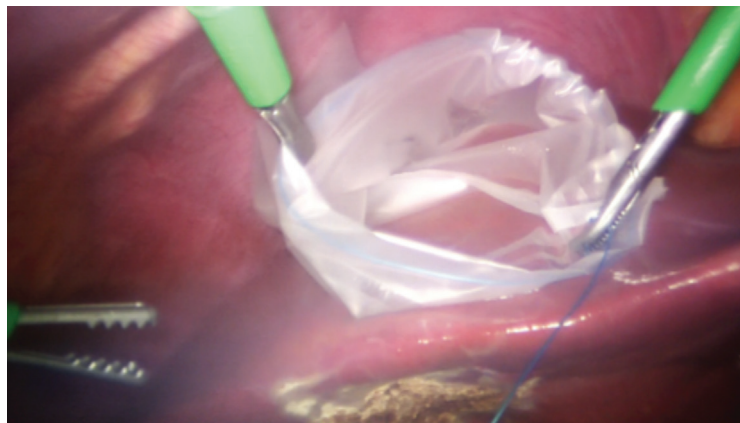


Figure 7 Placing the retrieval bag up over the liver.

gallbladder was placed inside the bag (Figure 8). The bag was fastened (Figure 9) and extracted through the umbilical port. When the surgery was finished, the problems in using RAMA retrieval bag included the number of bile leakages or stone spillages from

RAMA retrieval bag into the abdominal cavity, number of bag breakages, problems associated with opening the bag, tearing of tying material upon bag closure, difficulty in closing the bag, and retrieval bag obstruction at the port site were collected from surgeons.



Figure 8 Manipulation of the gallbladder inside the retrieval bag.

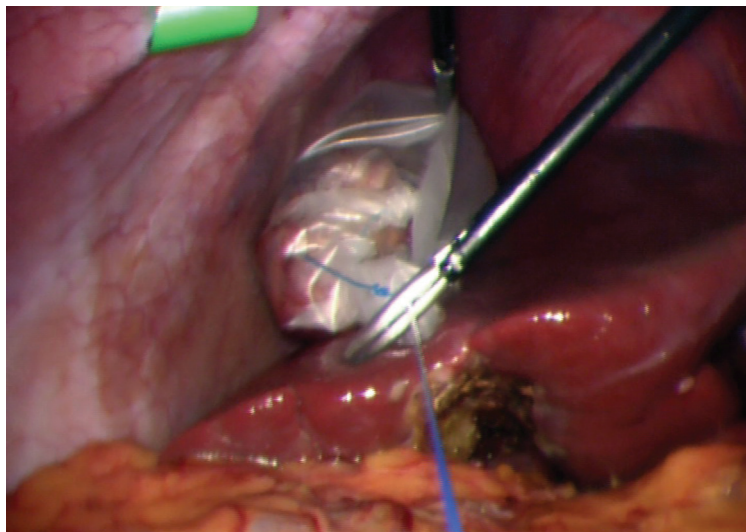


Figure 9 Swiping to close the bag.

Data analysis

The data were screened before analysis. Descriptive statistics, including frequencies and percentages were used to analyze problem in using the retrieval bag. The instrument used to assess the surgeons' opinions was analyzed in two parts. First, the separate items were analyzed with the Likert scale as an ordinal scale using

the medians and frequencies to measure central tendency and dispersion.²⁵ Second, a set of the items grouped into three main subscales was analyzed with the Likert scale as an interval scale using the mean and standard deviation to measure central tendency and dispersion. Cronbach's alpha test was used to identify *intercorrelations* among the grouped items of the three subscales.²⁶

Results

From January to April 2017, all 12 participating surgeons used RAMA retrieval bag on 110 patients undergoing LC. The data showed that there was no incidence of bile leakage or stone spillage from RAMA retrieval bag into the abdominal cavity, no problems associated with opening the bag, no bag breakages, no record of tearing of the tying material upon bag closure, and no RAMA retrieval bag obstructions at the port site. Port site extension was not required for any patients. The bag was somewhat difficult to close in only three cases (2.7%).

The mean score for evaluation of the overall items was 4.69 ± 0.37 (Table 1). A mean score greater than 4 points was computed from the analysis of all three subscales. The subscale scores were: 4.61 ± 0.47 for function of the retrieval bag, 4.67 ± 0.37 for usability of the retrieval bag, and 4.81 ± 0.39 for safety of using the retrieval bag. Most surgeons (7 of 12, 58.3%) assigned 5 points to all items that were grouped into these subscales (median = 5 points), indicating that the retrieval bag was very effective. In particular, 5 of the 12 surgeons (41.7%) assigned the lowest score to the item "Closing the bag is simple and the tying material does not disturb closing" on the usability subscale (median = 4 points).

Table 1. Participants' Opinions regarding Use of the Retrieval Bag (N = 12)

Variables	Min	Max	Median	n (%)	M \pm SD
Functions of the retrieval bag					
The retrieval bag is located in the vertical position, resulting in easy removal.	3	5	5	7 (58.3)	
Prevention of gallstone spillage from the gallbladder sac and enclosure of gallbladder inside the bag.	4	5	5	7 (58.3)	
Prevention of abdominal cavity contamination from gallbladder perforation during gallbladder removal.	4	5	5	9 (75.0)	
Subscale					4.61 \pm 0.47
Usability of the retrieval bag					
Easy to hold the bag with grasper forceps. The tying material is not disturbed while holding the bag.	4	5	5	7 (58.3)	
The bag is easy to fold and insert through the port.	4	5	5	10 (83.3)	
The open end of the bag is easy to open and does not collapse.	4	5	5	10 (83.3)	
Closing the bag is simple and the tying material does not disturb closing.	3	5	4	5 (41.7)	
The bag is flexible and remains in the proper structure during use.	4	5	5	10 (83.3)	
Subscale					4.67 \pm 0.37
Safety of using the retrieval bag					
The bag does not break during use.	4	5	5	9 (75.0)	
The material used to make the bag is smooth and does not injure tissue during insertion into the abdominal cavity.	4	5	5	10 (83.3)	
The tying material is long enough that it can be pulled out of the port to prevent losing the bag in the abdomen or forgetting to extract the bag from the abdominal cavity.	4	5	5	10 (83.3)	
Subscale					4.81 \pm 0.39
Total					4.69 \pm 0.37

Note. SD = standard deviation; n = number of surgeons who rated the item with the median score. Effectiveness score: 1 = very ineffective, 2 = ineffective, 3 = neither ineffective nor effective, 4 = effective, 5 = very effective.

Discussion

Along with the further development of RAMA retrieval bag, the problems associated with the previous version were considered, and its design was changed to improve the usability of the bag and increase patient safety. The needs of surgeons and patient safety must be taken into account during the design process.²⁷ A better understanding of reported problems and identification of any complications can reduce the risk of error and improve patient safety.²⁸

The absence of problems associated with using the new retrieval bag indicates that the design of RAMA retrieval bag is suitable for use by surgeons removing the gallbladder from the abdominal cavity. The bag was somewhat difficult to close in only three cases (2.7%). The explanation was that in the early stages of developing a new version, surgeons were not familiar with using nylon thread. The cause of adverse incidents is assumed to be related to device design, which may be harmful to patients.¹⁷ If a user appears to have a problem with a device, and presuming that a device design problem exists,²¹ sharing this information with others can help to identify a design error that may contribute to poor patient outcomes.^{20, 29}

The surgeons' scores for the individual items and group subscale on functions of RAMA retrieval bag show that RAMA retrieval bag is very effective. These scores indicate that RAMA retrieval bag can prevent stone spillage into the abdominal cavity and avoid abdominal contamination. Use of a retrieval bag to remove the gallbladder during LC is important to prevent adverse events associated with bile leakage and stone spillage into the abdominal cavity.^{5, 30} In patients with gallbladder cancer, the use of retrieval bags has been recommended to minimize the risk of abdominal dissemination and port site metastasis.^{31, 32} The cone shape of RAMA retrieval bag prevents the gallbladder from obstructing the port incision and allows surgeons to easily remove the gallbladder through the port site. Siddiqui et al.³³ reported that difficult removal

of the gallbladder from the port site is an important factor in post LC pain. The results of the present study indicate that RAMA retrieval bag functions properly and efficiently. In general, the device design must be relevant to the purpose for which it is intended.¹⁷

Analysis of the items and subscale on the usability of RAMA retrieval bag also indicate that the bag is very effective. These scores indicate that RAMA retrieval bag is simple to use and easy to insert through the port. Additionally, the bag is easy to keep open and placement of the gallbladder inside is convenient. Usability testing takes into account the complexity of the device and its ease of use. If a device is difficult to use, a risk is likely to exist.²⁹ However, most surgeons assigned the lowest score to the simplicity of closing the bag and ease of knot tying during closure because the bag was somewhat difficult to close in three cases. This result indicates that problems associated with fastening the knot may have been caused by the surgeons' techniques. With respect to the surgeons' experience relative to this study, the procedures could not be controlled to ensure that all surgeons used the same technique when closing the retrieval bag. This may have resulted in improper use of RAMA retrieval bag. There is no consensus on the optimal retrieval method.⁷ Use of a medical device without adequate information before an operation can result in errors.¹⁶ User error may result from inattention or failure to understand instructions. However, a poor device design can directly contribute to user error. Fairbanks and Wears²¹ stated that the design of medical devices can significantly influence patient safety. Improved safety requires an instruction manual to ensure that surgeons use RAMA retrieval bag correctly.

The scores for the items and subscale on the safety of using the bag indicate that the bag is very safe. These scores show that RAMA retrieval bag has more stretchiness and elasticity, which prevents the bag from breaking during use. The long thread outside the port is used to remind the surgeon not to

leave the gallbladder inside the abdominal cavity. The smooth surface of the plastic material allows for adjustment of the bag's flexibility upon removal, which reduces port site trauma. In patients with large gallbladders, extension of the port site incision is commonly needed to remove the bag from the abdominal cavity.⁷ RAMA retrieval bag resolves this issue because the surgeon cuts the thread above the knot and manipulates the gallbladder content to reduce the gallbladder size before extraction of the bag. The design of this new version thus makes the bag simple and safe to use. In general, the design of medical devices should consider utility and conform to the users' work patterns.²⁷ In this study, evaluation of the effectiveness of RAMA retrieval bag was based on the participating surgeons' opinions. Surgeons' reactions to the device design and problems during its use can also be indicators of device effectiveness.³⁴

RAMA retrieval bag has a concave shape at the open end and using nylon thread makes it easy to open. The closing system with nylon thread keeps the bag tightly closed, preventing the specimen leaving from the bag. Moreover, the other long side of nylon thread is outside the abdomen. This allows the bag to be easily removed and no need to use other tools to assist in the removal of the retrieval bag from the abdomen. The cost of the new version is inexpensive. The total cost of RAMA retrieval bag used on 110 patients was 44,000 baht (1,329.54 USD) compared to imported specimen retrieval bags which cost 110,000 baht (3,323.86 USD). Thus RAMA retrieval bag was much less expensive for patients who underwent LC [66,000 baht (1994.32 USD)] at our hospital.

Limitations

This study included participating surgeons from one medical institution to evaluate RAMA retrieval bag. Accordingly, this will limit any generalization to other surgeons who used RAMA retrieval bag in different contexts at other hospitals.

Conclusions and Implications for Nursing Practice

The findings from this study revealed that the new version of retrieval bag is safe to use, ease to handle, and more flexibility to use in LC. The use of this bag reduce patients' risk from surgery and accepted by most surgeons in our hospital. It also makes perioperative nurses convenient and save time for preparing instruments during remove gallbladder from the abdominal cavity which will promote patient safety.

In addition, this study is an example of how a design and development project should be conducted, particularly in nursing practice, to promote the safe use of medical devices in the perioperative period during which patients are unable to advocate for themselves. In this study, problem reporting was used to indicate design errors and surgeons' opinions, allowing us to identify design errors and evaluate the effectiveness of the new retrieval bag. Errors may occur at several points throughout the design and development process, and those unnoticed in the operating room can significantly influence patient safety. This study illustrates how the authors responded to the challenge of developing a gallbladder retrieval bag that is safer, more effective, and less expensive than other retrieval bags. Furthermore, the authors intended that the design of this retrieval bag in different sizes can be used to collect enlarged specimens such as prostate glands, kidney tumors, and liver mass in other types of laparoscopic surgery. Mahidol University, with which the authors are affiliated, received Patent No. 13232 on 3 November 2017 for this new RAMA retrieving bag.

Acknowledgement

The authors thank the participating surgeons for their opinions and suggestions during the development and evaluation of the new retrieval bag and also to their other team members.

Conflict of interest: None declared.

References

1. Karim T, Kadyal A. A comparative study of laparoscopic vs. open cholecystectomy in a suburban teaching hospital. *J Gastrointest Dig Syst.* 2015;5(6):1–5. DOI: <http://dx.doi.org/10.4172/2161-069X.1000371>
2. Stavroulis A, Mentsa M, Yoong W. Methods for specimen removal from the peritoneal cavity after laparoscopic excision. *TOG.* 2013;15:26–30. DOI: <http://dx.doi.org/10.1111/j.1744-4667.2012.00148.x>
3. Singh SP, Singh U, Singh CP, Chaturvedi J, Shekhar C. Laparoscopic cholecystectomy v/s open cholecystectomy: A comparative study at LLRM Medical College & Hospital, Meerut. *IJPHRD.* 2012;3(1):72–4.
4. Faour R, Sultan D, Houry R, Faour M, Ghazal A. Gallstone-related abdominal cystic mass presenting 6 years after laparoscopic cholecystectomy: A case report. *Int J Surg Case Rep.* 2017;32:70–2. DOI: <http://dx.doi.org/10.1016/j.ijscr.2017.01.059>
5. Zehetner J, Shamiyeh A, Wayand W. Lost gallstones in laparoscopic cholecystectomy: All possible complications. *Am J Surg.* 2007;193:73–8. DOI: <http://dx.doi.org/10.1016/j.amjsurg.2006.05.015>
6. Endo catch™ gold disposable specimen pouch [Internet]. Covidien company. 2012 [cited April, 2017]. Available from: <http://www.covidien.com/imageServer.aspx?contentID=38627&contentType=application/pdf>.
7. Majid MH, Meshkat B, Kohar H, El Masry S. Specimen retrieval during elective laparoscopic cholecystectomy: Is it safe not to use a retrieval bag? *BMC Surg.* 2016;16(1): 64. DOI: <http://dx.doi.org/10.1186/s12893-016-0181-y>
8. Shyam DC, Baruah AJ, Topno N. Cheap retrieval bag for laparoscopic cholecystectomy. *East Cent Afr J surg.* 2012;17(2):110–1. <https://www.ajol.info/index.php/ecajs/article/view/84259/74268>
9. Stavrou G, Fotiadis K, Panagiotou D, Faitatzidou A, Kotzampassi K. Homemade specimen retrieval bag for laparoscopic cholecystectomy: A solution in the time of fiscal crisis. *Asian J Endosc Surg.* 2015;8(2):223–5. DOI: <http://dx.doi.org/10.1111/ases.12165>
10. Bergmann JHM, Noble A, Thompson M. Why is designing for developing countries more challenging? modelling the product design domain for medical devices. *Procedia Manuf.* 2015;3:5693–8. DOI: <https://doi.org/10.1016/j.promfg.2015.07.792>
11. Crook C. Advocacy: How far would you go to protect your patients? *AORN J.* 2016;103(5):522–6. DOI: <https://doi.org/10.1016/j.aorn.2016.03.009>
12. Bhumisirikul P, Kongdan Y, Pongchairerks P. Low-priced specimen retrieval sac for laparoscopic cholecystectomy. *ELSA.* 1999;3(3):47–9.
13. Bhumisirikul P. Ramathibodi bag version 2 : The newly designed gallbladder retrieval sac for laparoscopic cholecystectomy. *Rama Nurs J* 2005;2(11):77–83.
14. Bunting DM. Port-site hernia following laparoscopic cholecystectomy. *JSLs.* 2010;14(4):490–7. DOI: <http://dx.doi.org/10.4293/108680810X12924466007728>
15. Sharma R, Mehta D, Goyal M, Gupta S. The earliest presenting umbilical port site hernia following laparoscopic cholecystectomy: A case report. *J Clin Diagn Res.* 2016;10(7):PD18–PD9. DOI: <http://dx.doi.org/10.7860/JCDR/2016/20460.8205>
16. Mattox E. Patient Safety. Medical devices and patient safety. *Crit Care Nurse.* 2012;32(4):60–8. DOI: <http://dx.doi.org/10.4037/ccn2012925>
17. Blandford A, Furniss D, Vincent C. Patient safety and interactive medical devices: Realigning work as imagined and work as done. *Clin Risk.* 2014;27(5):107–10. DOI: <http://dx.doi.org/10.1177/1356262214556550>
18. Castner J, Sullivan SS, Titus AH, Klingman KJ. Strengthening the role of nurses in medical device development. *J Prof Nurs.* 2016;32(4):300–5. DOI: 10.1016/j.profnurs.2016.01.002
19. McClelland M, Kleinke D. Improving lives using multidisciplinary education: partnering to benefit community, innovation, health, and technology. *J Nurs Educ.* 2013;52(7):406–9. DOI: 10.3928/0148483420130610-01
20. Swayze SC, Rich SE. Promoting Safe Use of Medical Devices. *Online J Issues Nurs.* 2012;17(1):11–9.
21. Fairbanks RJ, Wears RL. Hazards with medical devices: The role of design. *Ann Emerg Med.* 2008;52(5):519–21. DOI: <http://dx.doi.org/10.1016/j.annemergmed.2008.07.008>
22. Design for patient safety: User testing in the development of medical devices [Internet]. 2010 [cited January 10, 2018]. Available from: file:///C:/Users/NSA/Downloads/1184_User%20testing%20of%20medical%20devices_access.pdf.

23. Fiedler BA. Evaluating new medical devices purchases. In: Fiedler BA, editor. *Managing Medical Devices within a Regulatory Framework*. New York: Elsevier; 2016. p. 179–201.
24. Richey RC, Klein JD. *Design and development research: Methods, strategies, and issues*. 1st ed. Mahwah, New Jersey: Lawrence Erlbaum; 2007.
25. Sullivan GM, Jr ARA. Analyzing and interpreting data from Likert-Type scales. *J Grad Med Educ*. 2013;5(4): 541–2. DOI: <http://dx.doi.org/10.4300/JGME-5-4-18>
26. Joshi A, Kale S, Chandel S, Pal DK. Likert scale: Explored and explained. *Br J Appl Sci Technol* 2015;7(4):396–403. DOI: <http://dx.doi.org/10.9734/BJAST/2015/14975>
27. Martin JL, Norris BJ, Murphy E, Crowe JA. Medical device development: The challenge for ergonomics. *Appl Ergon*. 2008;39(3):271–83. DOI: <http://dx.doi.org/10.1016/j.apergo.2007.10.002>
28. Rich S, El-Shammaa M. Medical device reporting -- a model for patient safety. *Am Nurse Today*. 2017;12(2): 10–2. <https://ejournal.mahidol.ac.th/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=121353619&site=ehost-live>
29. Knudson L. Management Connections: Ensuring safe use of medical devices. *AORN J*. 2013;98(1):C1–C10. DOI: [https://doi.org/10.1016/S0001-2092\(13\)00606-6](https://doi.org/10.1016/S0001-2092(13)00606-6)
30. Kao CC, Cha TL, Sun GH, Yu DS, Chen HI, Chang SY, et al. Cost-effective homemade specimen retrieval bag for use in laparoscopic surgery: Experience at a single center. *Asian J Surg*. 2012;35(4):140–3. DOI: <http://dx.doi.org/10.1016/j.asjsur.2012.04.025>
31. Richardson DB, Chesney TR, Englesakis M, Govindarajan A, Cleary SP, Swallow CJ. Trends in port-site metastasis after laparoscopic resection of incidental gallbladder cancer: A systematic review. *Surgery*. 2017;161:618–27. DOI: <http://dx.doi.org/10.1016/j.surg.2016.08.007>
32. Jin K, Lan H, Zhu T, He K, Teng L. Gallbladder carcinoma incidentally encountered during laparoscopic cholecystectomy: How to deal with it. *Clin Transl Oncol*. 2011;13(1):25–33. DOI: <http://dx.doi.org/10.1007/s12094-011-0613-1>
33. Siddiqui NA, Azami R, Murtaza G, Nasim S. Postoperative port-site pain after gall bladder retrieval from epigastric vs. umbilical port in laparoscopic cholecystectomy: A randomized controlled trial. *Int J Surg*. 2012;10(4):213–6. DOI: <http://dx.doi.org/10.1016/j.ijsu.2012.03.008>
34. Tracey MW. Design and development research: A model validation case. *Education Tech Research Dev*. 2009; 57:553–71. DOI: <http://dx.doi.org/10.1007/s11423-007-9075-0>

การพัฒนาถุงรองรับถุงน้ำดีรามานิธิเพื่อความปลอดภัยของผู้ป่วย: นวัตกรรมทางการแพทย์

เพียรจิตต์ ภูมิสิริกุล ณัฐชา เจียรนิกุลชัย*

บทคัดย่อ: หนึ่งในปัญหาสำคัญสำหรับการผ่าตัดเอาถุงน้ำดีออกผ่านกล้อง คือ น้ำดีและก้อนนิ่วตกกระจ่ายลงสู่ช่องท้อง ซึ่งจะส่งผลให้เกิดการปนเปื้อน ดังนั้นถุงรองรับถุงน้ำดีจึงใช้เพื่อป้องกันปัญหานี้ การศึกษานี้มีวัตถุประสงค์ เพื่อออกแบบและพัฒนาถุงรองรับถุงน้ำดีที่มีอยู่ให้มีความปลอดภัยสำหรับผู้ป่วยและเพื่อประเมินประสิทธิผลของถุงรองรับถุงน้ำดีรุ่นใหม่ การศึกษานี้ได้แบ่งดำเนินการเป็น 2 ขั้นตอน คือ การออกแบบและพัฒนาถุงรองรับถุงน้ำดีรุ่นใหม่ และการประเมินประสิทธิผลของถุงรองรับถุงน้ำดี ซึ่งประเมินประสิทธิผลโดยการเก็บข้อมูลจากบันทึกปัญหาจากการใช้ถุงรองรับถุงน้ำดีในผู้ป่วยที่ได้รับการผ่าตัดเอาถุงน้ำดีออกผ่านกล้องจำนวน 110 ราย ระหว่างเดือนมกราคม 2560 ถึง เมษายน 2560 และการประเมินความคิดเห็นของศัลยแพทย์จากการใช้ถุงรองรับถุงน้ำดีในการผ่าตัดผ่านกล้อง วิเคราะห์ข้อมูลโดยใช้สถิติเชิงพรรณนา

ผลการวิจัย จากบันทึกปัญหาภายหลังการผ่าตัดผู้ป่วยทุกราย พบว่า ไม่มีปัญหาจากการนำเอาถุงรองรับถุงน้ำดีรามานิธิติดออกจากช่องท้อง และไม่พบปัญหาเรื่องถุงรองรับถุงน้ำดีแตกหรือฉีกขาด การรัดปิดถุงรองรับถุงน้ำดีทำได้ค่อนข้างยากในผู้ป่วย 3 ราย (2.7%) สำหรับการประเมินความคิดเห็นของศัลยแพทย์ พบว่า คะแนนเฉลี่ยในการประสิทธิภาพของถุงรองรับถุงน้ำดีโดยรวมมีประสิทธิภาพอยู่ในระดับมากที่สุด ทั้งในด้านความปลอดภัยและในด้านการทำงานของถุงรองรับถุงน้ำดีได้คะแนนสูง

ถุงรองรับถุงน้ำดีรามานิธิรุ่นใหม่ปากถุงเปิดอัดได้ง่าย ช่วยป้องกันไม่ให้ชิ้นเนื้อหลุดออกจากถุงทำให้ผู้ป่วยปลอดภัย ค่าใช้จ่ายของถุงรองรับถุงน้ำดีรามานิธิต่ำกว่าถุงรองรับถุงน้ำดีชนิดอื่น ดังนั้นการใช้ถุงรองรับถุงน้ำดีนี้สามารถลดความเสี่ยงของผู้ป่วยจากการผ่าตัดและได้รับการยอมรับโดยศัลยแพทย์ส่วนใหญ่ในโรงพยาบาลของเรา นอกจากนี้ยังทำให้พยาบาลผ่าตัดสามารถเตรียมเครื่องมือผ่าตัดได้สะดวกและประหยัดเวลาในการเตรียมเครื่องมือ

Pacific Rim Int J Nurs Res 2018; 22(3) 264-277

คำสำคัญ: การออกแบบเครื่องมือ ถุงน้ำดีรามานิธิ การผ่าตัดเอาถุงน้ำดีออกผ่านกล้อง เครื่องมือแพทย์ ความปลอดภัยของผู้ป่วย

เพียรจิตต์ ภูมิสิริกุล พย.ม.(การบริหารการพยาบาล) งานการพยาบาลผ่าตัด
ฝ่ายการพยาบาลโรงพยาบาลรามานิธิ คณะแพทยศาสตร์โรงพยาบาลรามานิธิ
มหาวิทยาลัยมหิดล
ติดต่อที่: ณัฐชา เจียรนิกุลชัย*, RN, PhD. ผู้ช่วยศาสตราจารย์
โรงเรียนพยาบาลรามานิธิ คณะแพทยศาสตร์โรงพยาบาลรามานิธิ
มหาวิทยาลัยมหิดล E-mail: natthacha.chi@mahidol.ac.th