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TJS

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ABSTRACTS

171 Abstracts of the 48th Annual Scientific Congress of The Royal College of Surgeons of Thailand, 27-29 July 2023 (Part II)
(Only published in printed version)

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The Thai Journal of Surgery is the official publication of The Royal College of Surgeons of Thailand and is issued quarterly.

The Thai Journal of Surgery invites concise original articles in clinical and experimental surgery, surgical education, surgical history, surgical techniques, and devices, as well as review articles in surgery and related fields. Papers in basic science and translational medicine related to surgery are also welcome.

Aim & Scope

The Thai Journal of Surgery is dedicated to serving the needs of the members of The Royal College of Surgeons of Thailand, specifically the younger researchers and surgical trainees who wish to have an outlet for their research endeavors. The Royal College strives to encourage and help develop Thai Surgeons to become competent researchers in all their chosen fields. With an international outlook, The Thai Journal of Surgery welcomes submissions from outside of Thailand as well.

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2. Corporate Author:

- The Committee on Enzymes of the Scandinavian Society for Clinical Chemistry and Clinical Physiology. Recommended method for the determination of gamma glutamyltransferase in blood. Scand J Clin Lab Invest 1976; 36:119-25.
- American Medical Association Department of Drugs. AMA drug evaluations. 3rd ed. Littleton: Publishing Sciences Group, 1977.

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- Chirappapha P, Arunnart M, Lertsithichai P, et al. Evaluation the effect of preserving intercostobrachial nerve in axillary dissection for breast cancer patient. Gland Surg 2019;8:599-608. doi:10.21037/gs.2019.10.06.

Abbreviations

Use only standard abbreviations of commonly used approved abbreviations. Avoid abbreviations in the title. The full term for which an abbreviation stands should precede its first use in the text unless it is a standard unit of measurement.

Statistics

All statistical analyses and the statistical software used must be concisely described. Descriptive statistics for quantitative variables must include an appropriate central tendency measure (e.g., mean or median) as well as a corresponding measure of spread (e.g., standard deviation or range or interquartile range). Categorical variables must be summarized in terms of frequency (counts) and percentage for each category. Ordinal variables can be summarized in terms of frequency and percentage, or as quantitative variables when appropriate. Statistical tests must be named and p-values provided to 3 decimal places. P-values less than 0.001 should be written "< 0.001" and p-values approaching 1 should be written "0.999".

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Randomized controlled trials should be analyzed using the intention-to-treat principle, and as treated analysis should be applied as well if there are significant cross-overs. Further details of statistical issues are available here (http://www.icmje.org/icmje-recommendations.pdf).

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(see Format https://bit.ly/3IaP4ZB)

Abstract: should be no more than 300 words in length, and written in a structured format, including the following headings: **Objective,** which can include some background material of 1 to 2 sentences in length, but mainly describing the research question; **Methods,** concisely describing the research design and data procurement; **Results,** describing the main findings of the study; and **Conclusion,** which should concisely answer the research question, and no more. Below the abstract, a list of keywords should be provided.

Main text: should be written in a structured format, including the following headings. **Introduction** should describe the rationale of the study within the context of current knowledge; the gap in knowledge with which the research study will fill must be clearly pointed out and a research question explicitly stated. **Methods (and patients, if applicable)** should clearly describe the details of research methodology and patient or research volunteer recruitment according to Guidelines for each type of research as listed above (…), and how the data was collected and analyzed. A short description of statistics used, and the software and references if appropriate, must be provided. A note on Ethics Committee approval, if applicable, must be given. **Results** should include data or summaries of patient or volunteer characteristics, summaries of risk factors or covariates and outcomes, presented in tabular, graphical or descriptions in the text as appropriate, without significantly duplicating one another. Results of statistical analyses must be clearly displayed and should include point estimates, standard errors, statistical tests, *p*-values, and 95% confidence intervals as detailed (…). Analyses not shown but

referred to must not change the conclusions or outcomes. **Discussion,** which must fully describe the implications of the research results, should include a concise literature review of previous published, related results. These related results must be compared with those of the authors' study, and the differences clearly stated along with plausible explanations. New unexpected findings, especially from subgroup analyses or those for which the research was not designed, should be considered hypothetical and stated as such. Any plausible, relevant clinical application should be indicated. Finally, any significant limitations of the study must be mentioned and possible extensions of research should be briefly provided. **Conclusion,** which should be concerned with answering the research question posed by the current study, should not be summarizing results of previous studies or recommendations. An **Acknowledgement** section can be added at the end of the article. The Reference list should be in the format as described previously.

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Use the common format. Emphasis is on clinician comprehension. The **Abstract** uses the same common structured format. In the **Main text,** the **Introduction,** in addition to the usual context setting and rationale, should also contain explanations and descriptions of basic science concepts at the level of the educated layman. The **Methods** section should still be concise with sufficient detail for others to replicate the experiment, but one or two paragraphs in between explaining basic processes in plain English would be helpful. In the **Results** section, similar conciseness is still the rule, but a brief simplified summary of the findings should be provided. In the **Discussion,** clinical implications should be clearly stated. The **Conclusion,** again, should answer the research question.

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Abstract: Need not be structured. State objective of the case presentation, present a summary of the case, the outcome and learning points in one concise paragraph.

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Special articles are often solicited and may have no standard structure. But some structure will aid understanding or entice readers.

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Original Article

Comparison of Local and Spinal Anesthesia in Elective Open Repair Primary Unilateral Inguinal Hernia in Rattanaburi Hospital

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Abstract

Background and Objective: Inguinal hernia is a common surgical condition, and surgery is considered the most effective treatment. This study compares the outcomes of inguinal hernia surgery performed under local and spinal anesthesia at Rattanaburi Hospital.

Methods: This study is a retrospective cohort study involving patients diagnosed with inguinal hernia who underwent treatment at Rattanaburi Hospital. The sample size is 33 patients per group. Data were analyzed using descriptive and inferential statistics, including the chi-square test, *T*-test, and repeated ANOVA.

Results: In the elective open repair primary unilateral inguinal hernia surgery study, 66 cases were analyzed, with 33 patients performed under local anesthesia and 33 patients under spinal anesthesia. In the group that received local anesthesia, one case (3.03%) experienced a complication of bradycardia during surgery. However, no complications were reported in the spinal anesthesia group during surgery. Regarding post-surgery complications within the first week, the local anesthesia group reported one case of seroma (3.03%). In contrast, the spinal anesthesia group had three cases of wound hematoma (9.09%), one case of seroma (3.03%), and three cases of urinary retention (9.09%). When comparing the surgical results using pain scores measured on the Visual Analog Scale (VAS), the average VAS pain scores at 6 hours, 24 hours, and 48 hours significantly differ between the two groups. During the one-month follow-up, both groups showed no need for treatment of recurrent cases. The average treatment cost for the local anesthesia group was 13,182.42 baht, while the spinal anesthesia group had an average price of 20,872.18 baht. The average cost difference between the two groups was 7,689.75 baht (p-value < 0.01). Patient satisfaction did not significantly differ between the two groups.

Conclusion: Inguinal hernia surgery performed with local anesthesia is a safe procedure with few complications and lower costs. A hospital stay is unnecessary, and postoperative pain levels are lower than those observed in the spinal anesthesia group, especially after 6 hours.

Keywords: Inguinal hernia, Local anesthesia, Hernia Surgery

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Introduction

Inguinal hernia represents a prevalent surgical pathology, constituting the majority, at 78%, of all hernia cases. The established therapeutic approach entails surgical intervention involving the application of MESH Graft, performed under general anesthesia (spinal block) or local anesthesia, as determined by the individual patient's clinical status. Several critical factors influence the management of inguinal hernia, including patient co-morbidities and the surgical expertise of the operating surgeon.[1,2] Surgical intervention in asymptomatic patients substantially reduces complications and mortality rates,[3] with reported decreases of up to 3% and 60-70%, respectively. Additionally, it is worth noting that many patients prefer general anesthesia (GA) primarily due to preoperative anxiety and apprehension regarding the surgical procedure.[4] The research conducted in Scotland revealed that the patients mostly selected General anesthesia at 91%, followed by Spinal anesthesia at 5% and local anesthesia at 3% respectively.[5] Regarding the anesthesia method or spinal anesthesia (spinal block), the patient must prepare before surgery at the hospital. After surgery, the patient will have to stay in the hospital for observation and monitoring for complications from anesthesia and analgesia. There are costs for hospital stays and travel expenses for patients and relatives. As for hernia surgery, local anesthesia is beginning to be applied in operation more. This surgery method allows effective treatment results, is safe, and has less post-operative wound pain. The patient can go home after the surgery with fewer complications from anesthesia and spinal anesthesia and save on hospital admission costs and relatives' travel. The research by Chawalit Songkhramyot[6] stated that elective open repair primary unilateral inguinal hernia using local anesthesia can be performed with fewer complications. The average hospital stay in the local anesthesia group was 26.48 hours, and the average spinal block was 45.98 hours. Besides, the average treatment cost in the regional anesthesia group was 7,951.65 baht. In contrast, the spinal anesthesia group was 10,020.08 baht, which was found to be a statistically significant difference.

The patient's pain after the surgery was compared and observed. After surgery, the results were assessed using a visual analog scale (VAS), which stated that during the first 12 hours after surgery, patients who had surgery with local anesthesia had less pain since they received spinal anesthesia. However, the pain in both groups was no different after 24 hours.[6] When comparing the duration of surgery, postoperative complications, and recurrence, there is no difference between both patient groups who received local anesthesia and spinal anesthesia.[7]

This hospital is in Surin Province, with a 120-bed community healthcare facility. The hospital has received surgical patient referrals from neighboring Sanom Hospital and Nonnarai Hospital. Over the past three years (2018-2020), they observed 17, 19, and 10 cases of hernia per 100,000 population. Due to the absence of a dedicated surgeon, all cases were referred to Surin Center Hospital. In response to the need for prompt and efficient treatment, this hospital has initiated inguinal hernia surgeries, employing spinal and local anesthesia techniques performed by a single surgeon. The researcher is collecting data to compare the outcomes of these surgeries, aiming to provide effective and safe treatment to patients.

Research Objective

Primary objective

Compare postoperative pain severity using the Visual Analog Scale (VAS) at 6, 24, 48, 72 hours, and 7 days in patients undergoing elective open repair primary unilateral inguinal hernia surgery using local and spinal anesthesia.

Secondary objective

Compare intraoperative and postoperative complications in patients undergoing elective open repair primary unilateral inguinal hernia surgery using local and spinal anesthesia.

To study the surgical outcome, such as returning to daily life after surgery, length of stay in hospital, and cost of medical care in patients undergoing elective open repair primary unilateral inguinal hernia surgery using local and spinal anesthesia.

Materials and Methods

This research is a retrospective cohort study in patients undergoing elective open repair primary unilateral inguinal hernia surgery using local and spinal.

Population and Sample group (Selection criteria)

The inclusion criteria: patients diagnosed with an inguinal hernia on one side and not had surgery before, patients aged 18 years or older who have been diagnosed with an inguinal hernia on one side, and surgery consent.

The exclusion criteria: patients with inguinal hernias on both sides, patients who have had an inguinal hernia on one side and have undergone surgery before and have recurred, patients with hydrocele, femoral hernia, or lipoma of cord, patients who are allergic to local anesthetics and NSAID painkillers, patients who bleed easily stop taking medication (coagulopathy), patients who cannot inject spinal anesthesia or unable to inject local anesthesia, patients who refuse treatment/refuse surgery and did not come to the appointment.

Surgery procedures

1. Prepare anesthetic by mixing 1% Xylocain 20 cc with 0.5% Bupivacaine 20 cc.

2. Start ilioinguinal-iliohypogastric nerve blocks by injecting anesthetic 2-2.5 centimeters inside and above the anterior pelvic bone, injecting with the tip of the needle under the external oblique aponeurosis, 10 cc, as shown in Figure 1.

3. Inject anesthetic into the surgical wound. Starting from the pubic tubercle, draw a straight line to the midpoint of the inguinal ligament, which is the position of the inguinal ring. Then, inject the anesthetic into the skin layers.

4. To apply the surgical wound to the skin and subcutaneous layers, use a knife and scissors. A blood vessel ligation is used instead of cutting the tissue with an electrocautery. When reaching the Scarpa fascia layer, anesthetic is injected into this layer again because this layer is a barrier to the anesthetic from descending, and there are often nerves penetrating this layer, and external oblique aponeurosis comes out.

5. Inject anesthetic under the external oblique aponeurosis to push the ilioinguinal nerve at the top of the spermatic cord.

6. Cut open the external oblique aponeurosis with care not to injure the ilioinguinal and Ilihypogastric nerve, as shown in Figure 2.

7. Dissect the spermatic cord from the surrounding tissue.

8. Look for the hernia sac, then inject anesthetic around the hernia sac. Be careful of pulling on the hernia sac too much, which may cause the patient to have discomfort at the umbilicus. Cut up to the neck of the hernia sac (Neck of hernia sac), as shown in Figure 3.

9. Sew the lower edge of the mesh, starting from the inside, beyond the pubic tubercle, at least 2 centimeters, beginning from the rectus sheath area. Sew a continuous running suture through the pubic tubercle to the internal ring, as shown in Figure 4.

10. Prepare space for placing the mesh between the external oblique aponeurosis and internal oblique aponeurosis and sew the mesh.

11. Sew the external oblique aponeurosis to close the inguinal canal. Sew it to close layer by layer to the skin.

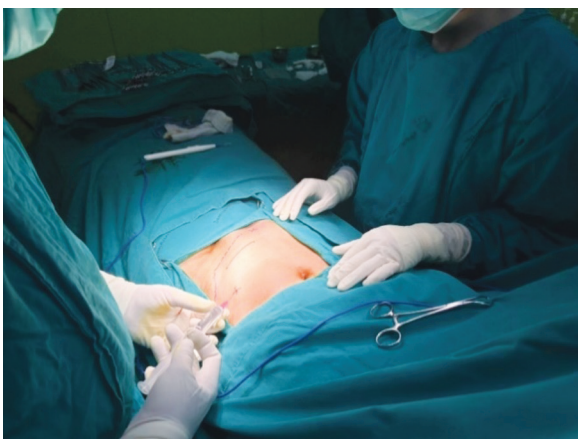

Figure 1

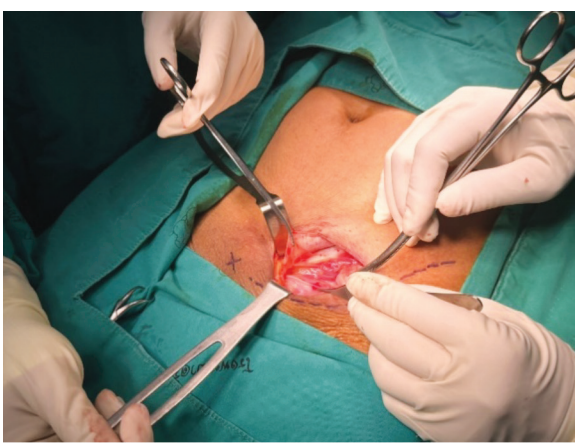

Figure 2

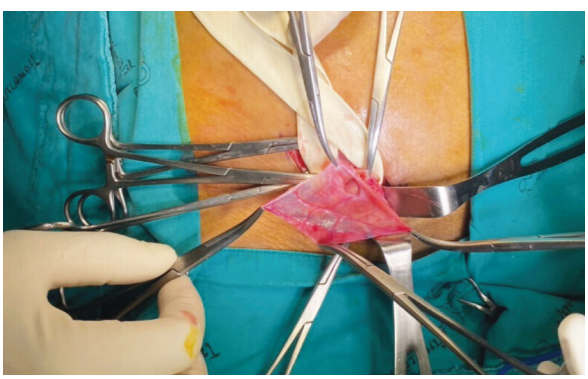

Figure 3

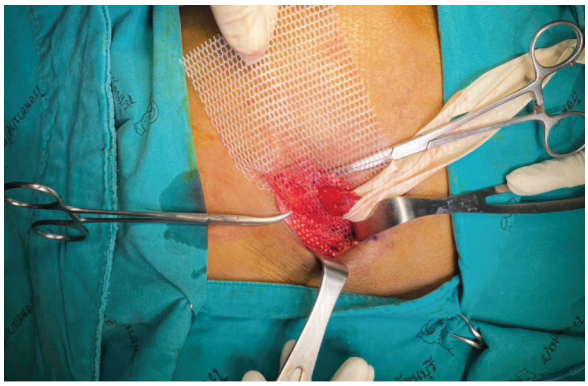

Figure 4

Example size

This sample size calculator is used for a study that compares continuous outcomes between two independent groups from Zamani-Ranani's research.[7]

The mean VAS at 3 hours period after surgery of the LA group was 22.00, SD = 4.19; the mean VAS at 3 hours period after surgery of the SA group was 31.33, SD = 13.08, Alpha = 0.01, Z (0.99), Beta = 0.10, Z (0.90), Sample size: LA group = 33, SA group = 33.

Sampling

All patients diagnosed with inguinal hernia were included in the study through a simple random sampling method. We utilized computer-generated random number tables to select participants based on the calculated sample size.

Data collection

The researcher designed a comprehensive data recording form for the study. Information was gathered through a questionnaire that covered various variables, including age, congenital diseases, vital signs, weight, height, body mass index, anesthesia method, blood loss during surgery, intraoperative and postoperative complications, postoperative pain levels assessed via the Visual Analog Scale (VAS) at 6, 24, 48, 72 hours, and 7 days after surgery, as well as the length of hospital stay.

Data analysis

The researcher uses the STATA program version 10.1 for processing and analyzing data.

1. Utilize statistical methods to describe data. When the data follows a normal distribution, present the mean and standard deviation; for data distributed non-normally, provide the median, interquartile range, maximum, and minimum values.

2. Apply inferential statistics, such as the chi-square or Fisher's exact test for categorical variables, and employ independent *t*-tests and Mann-Whitney U tests for quantitative variables following normal and non-normal distributions, respectively.

3. Conduct a comparative analysis of postoperative pain levels, assessed using the Visual Analog Scale (VAS) at 6, 24, 48, 72 hours, and 7 days, in patients undergoing inguinal hernia surgery with either local anesthesia or spinal anesthesia. Perform a repeated measures analysis using repeated measures ANOVA.

Results

From a study of 33 cases of local anesthesia and 33 cases of spinal anesthesia, the average age was 64.42 and 67.66, respectively (*p*-value 0.22). Most of the 33 cases were male (100%) and 31 cases (93.94%), respectively (*p*-value 0.15). The most indirect type was found, 19 cases (57.58%) and 21 cases (63.64%), respectively (*p*-value 0.21). Most were on the right side, 24 cases (72.73%) and 20 cases (60.61%), respectively (*p*-value 0.29), mean BMI of is 22.78 and 22.31, respectively (*p*-value 0.51), mean SBP 131.36 and 128.15, respectively (*p*-value 0.10), mean DBP 82.63 and 77.72 respectively (*p*-value 0.01), mean BT (°C) 36.75 and 36.80 respectively (*p*-value 0.32), mean HR (bpm) 85.75 and 84.78 respectively (*p*-value 0.59), mean RR (/min) 19.75 and 19.87 respectively (*p*-value 0.39) The majority of ASA status was at level 2, the most being 21 cases (63.64%) and 28 cases (84.85%), respectively (*p*-value 0.07), mean blood loss (ml) 4.63 and 4.0, respectively (*p*-value 0.05), as shown in Table 1.

When comparing complications of inguinal hernia surgery using local anesthesia and spinal anesthesia, Bradycardia complication was found in 1 case (3.03%) during surgery in the group using local anesthesia. In contrast, the spinal anesthesia group had no complications during surgery. As for complications after surgery within 7 days, it was found that the group using local anesthesia found 1 seroma (3.03%), while the spinal anesthesia group found wound hematoma 3 cases (9.09%), seroma 1 case (3.03%) and urinary retention 3 cases (9.09%), as shown in Table 2.

When comparing the results of inguinal hernia surgery using local and spinal anesthesia, the average operation time was 69.39 minutes and 48.12 minutes (*p*-value < 0.01).

Table 1 Characteristics of patients

	Local anesthesia (n = 33)	Spinal anesthesia (n = 33)	*p*-value
Age (mean ± SD)	64.42 ± 11.71	67.66 ± 9.92	0.22
Gender (%)			0.15
Male	33 (100)	31 (93.94)	
Female	0 (0)	2 (6.06)	
Types of Inguinal hernia (%)			0.21
Indirect	19 (57.58)	21 (63.64)	
Direct	1 (3.03)	4 (12.12)	
Combine	13 (39.39)	8 (24.24)	
Side (%)			0.29
Left	9 (27.27)	13 (39.39)	
Right	24 (72.73)	20 (60.61)	
BMI (kg/m^2)	22.78 ± 2.88	22.31 ± 2.97	0.51
SBP (mmHg)	131.36 ± 7.62	128.15 ± 8.43	0.10
DBP (mmHg)	82.63 ± 5.82	77.72 ± 7.95	0.01
BT (°C)	36.75 ± 0.25	36.80 ± 0.21	0.32
HR (bpm)	85.75 ± 7.13	84.78 ± 7.46	0.59
RR (/min)	19.75 ± 0.66	19.87 ± 0.48	0.39
ASA status (%)			0.07
1	3 (9.09)	0 (0)	
2	21 (63.64)	28 (84.85)	
3	9 (27.27)	5 (15.15)	
Anesthetic amount (ml)	37.27 ± 6.74		
Blood loss (ml)	4.63 ± 1.29	4.0 ± 1.29	0.05

Table 2 Comparing complications of elective open repair primary unilateral inguinal hernia surgery using local anesthesia and spinal anesthesia

	Local anesthesia (n = 33)	Spinal anesthesia (n = 33)
Intraoperative (%)		
Arrhythmias	0	0
Anaphylaxis	0	0
Pain needing sedation	0	0
Hypotension	0	0
Bradycardia	1 (3.03)	0
Postoperative Complications (%)		
Wound infection	0	0
Wound hematoma	0	3 (9.09)
Seroma	1 (3.03)	1 (3.03)
Testicular pain/swelling	0	0
Urinary retention	0	3 (9.09)
Headache	0	0
Respiratory complication	0	0

Table 3 Comparing the result of elective open repair primary unilateral inguinal hernia surgery using local anesthesia and spinal anesthesia

	Local anesthesia (n = 33)	Spinal anesthesia (n = 33)	*p*-value
Operation time (mins)	69.39 ± 19.87	48.12 ± 14.89	< 0.01
VAS			
6 hr.	3.66 ± 0.92	2.54 ± 1.82	< 0.01
24 hr.	3.45 ± 0.90	4.45 ± 0.97	< 0.01
48 hr.	3.06 ± 1.17	3.69 ± 1.13	0.02
72 hr.	1.60 ± 0.60	1.87 ± 0.78	0.11
7 days	0.39 ± 0.49	0.36 ± 0.48	0.80
Length of stay (hours)	6.12 ± 1.02	82.18 ± 52.31	< 0.01
Recurrence (0-1 month)	0	0	
Hospital cost	13,182.42 ± 4,394.06	20,872.18 ± 7,278.49	< 0.01
Patient satisfaction (5 scores)			0.30
4	3 (9.09)	1 (3.03)	
5	30 (90.91)	32 (96.97)	

The average VAS pain scores at 6 hours were 3.66 ± 0.92 and 2.54 ± 1.82, respectively. The researcher also found that the spinal anesthesia group had less pain and was significantly different (*p*-value < 0.01). The mean VAS scores at 24 hours were 3.45 ± 0.90 and 4.45 ± 0.97, respectively. Besides, the local anesthesia group had less pain and was significantly different (*p*-value < 0.01). The mean VAS scores at 48 hours were 3.06 ± 1.17 and 3.69 ± 1.13, respectively. The local anesthesia group had less pain and was significantly different (*p*-value = 0.02). The mean VAS scores at 72 hours were 1.60 ± 0.60 and 1.87 ± 0.78, respectively. It was found that the two groups were not significantly different. (*p*-value = 0.11) The mean VAS scores at 7 days were 0.39 ± 0.49 and 0.36 ± 0.48, respectively. It was found that there were no statistically significant differences. (*p*-value = 0.80) As for the days of hospital stay in the local anesthesia group, there will be no hospital stay but will stay there for 6.12 ± 1.02 hours, which is different from the spinal anesthesia group. It was found that the average hospital stay was 82.18 ± 52.31 hours. In addition, the follow-up treatment results within 1 month found that both groups had not returned to treatment again. When comparing treatment costs, it was found that the local anesthesia group had an average cost of 13,182.42 baht, and the spinal anesthesia group had an average cost of 20,872.18 baht. It was found to be a statistically significant difference. (*p*-value < 0.01) There was no difference in patient satisfaction between the two groups, as shown in Table 3.

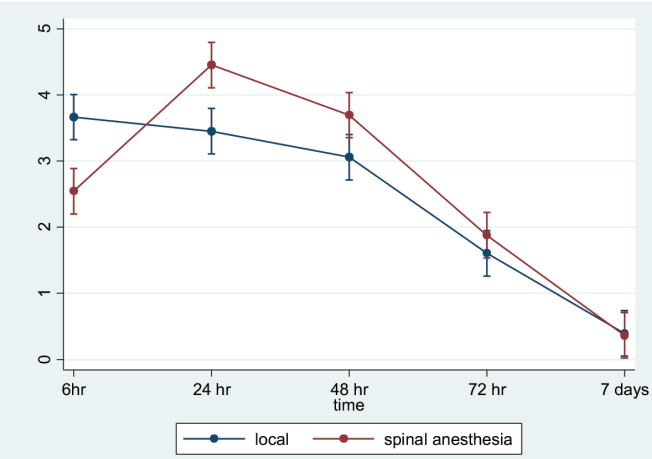

Figure 5 The results of the comparison of pain severity scores between 2 groups of patients

Discussion

Inguinal hernia surgery performed under local anesthesia has witnessed growing popularity. Patients anticipate a swifter recovery, enabling them to promptly return to their daily routines and normal occupational activities.[8] Return to daily activities and normal occupations faster.[8] Local anesthesia (LA) is frequently used, and this method causes pain during surgery. 85% of patients experience pain during surgery, but the majority still prefer this method.[9] The most used anesthesia technique is injecting anesthesia into the spinal block, which has the advantage of avoiding paralytic agents and endotracheal intubation.[10]

However, postoperative complications, such as patients with urinary retention, can often be found after the surgery. Local anesthesia has fewer postoperative complications. The results of this study found that the data from Table 1 from the general evaluation of the primary data, for the most part, were similar between the local anesthesia and anesthesia groups. In spinal studies, where group baseline tabulations indicate genuine or significant differences between groups, selecting covariates based on significance tests for baseline differences may lead to omitted variables. However, no differences were found between the 2 groups in this study.

In comparing complications arising from inguinal hernia surgery conducted under local anesthesia and spinal anesthesia, postoperative complications were lower using local anesthesia. This finding aligns with a study conducted by Courtney J. Balentine and colleagues,[11] which demonstrated that the utilization of local anesthesia resulted in a 0.6% reduction in postoperative complications among patients aged 75 years and older, with a 95% confidence interval of -0.11 to -1.13. This study underscores the advantages of using local anesthesia in patients undergoing inguinal hernia surgery, as it reduces the likelihood of postoperative complications. Among the group that underwent surgery with spinal anesthesia, there were notable instances of complications, including three cases of wound hematoma (all in patients aged 70 years or older), one case of seroma (in a 61-year-old patient), and three cases of urinary retention (all among the elderly individuals). Urinary retention is a common post-surgery complication, possibly exacerbated by the prevalence of inguinal hernias in older individuals who often experience urinary incontinence.[12] Furthermore, previous research has indicated that using short-acting lidocaine for spinal anesthesia mitigates the issue of urinary retention.[10] Consequently, further studies are warranted to comprehensively examine urinary retention incidence in this context.

When comparing the outcomes of inguinal hernia surgery performed under local anesthesia and spinal anesthesia, a notable disparity in mean operation times emerged, with durations of 69.39 minutes and 48.12 minutes, respectively (p-value < 0.01). This finding diverges from the results reported in the meta-analysis conducted by Lin Li et al.[4] and the randomized controlled trial (RCT) conducted by RN van Veen et al.,[13] both of which demonstrated significantly shorter overall surgery times in the local anesthesia group ($p < 0.001$). However, it is worth noting that this contrasts with the findings of the meta-analysis by Deepali Prakash et al.,[14] encompassing an RCT with 1,379 patients, which indicated no significant difference in surgery times between the two groups. In the current study, the extended duration of hernia surgery under local anesthesia may be attributed to the time required for the anesthetic to take effect and potential communication challenges, especially among patients with hearing impairments necessitating ongoing communication during the procedure. These factors introduce certain time constraints and limitations to the surgical process.

In comparing inguinal hernia surgeries under local anesthesia and spinal anesthesia, a significant disparity in mean operation times was noted, with durations of 69.39 minutes and 48.12 minutes, respectively (p-value < 0.01). These findings deviate from the results reported in Lin Li et al.'s meta-analysis[9] and RN van Veen et al.'s randomized controlled trial (RCT),[13] both of which indicated significantly shorter overall surgery times in the local anesthesia group ($p < 0.001$). However, this contrasts with the findings from Deepali Prakash et al.'s meta-analysis,[14] which encompassed an RCT involving 1,379 patients and showed no significant difference in surgery times between the two groups. In this study, the prolonged duration of hernia surgery under local anesthesia could be attributed to the waiting time for the anesthetic to take effect and challenges in communication, particularly among patients with hearing impairments necessitating during the procedure. These factors introduce time constraints and limitations to the surgical process.

The findings of this study compared pain scores among patients undergoing inguinal hernia surgery with local anesthesia and spinal anesthesia. At the 6-hour mark, the average pain score (VAS) was 3.66 ± 0.92 for the local anesthesia group and 2.54 ± 1.82 for the spinal anesthesia group, the spinal anesthesia group reporting less pain, signifying a statistically significant difference (p-value < 0.01), but 24-hour mark, with mean VAS scores of 3.45 ± 0.90 and 4.45 ± 0.97, the local anesthesia group reporting less pain signifying a statistically significant difference (p-value < 0.01). At 48 hours, the local anesthesia group had less pain, with mean VAS scores of 3.06 ± 1.17 compared to 3.69 ± 1.13 in the spinal anesthesia group (p-value = 0.02). However, at 72 hours and 7 days, no statistically significant differences were found (p-value = 0.11 and p-value = 0.80, respectively). These results align with the meta-analysis conducted by Deepali Prakash et al.,[14]

encompassing RCTs with 1,379 patients, demonstrating that patients in the local anesthesia group experienced less pain than those in the spinal anesthesia group. A long-acting local anesthetic (bupivacaine) lasting 4-6 hours might explain the reduced pain immediately after surgery. This study did not collect data on postoperative oral analgesic medications taken at home, which could be confounding. During 1-month follow-up, both groups showed no readmissions, aligning with findings from Kent Grosh and colleagues,[15] who observed no significant differences in mortality, morbidity, or readmissions within 30 days when comparing local anesthesia (LA) and spinal anesthesia (SA) to general anesthesia (GA). Regarding treatment costs, patients receiving local anesthesia had an average cost of 13,182.42 baht. In comparison, the spinal anesthesia group incurred an average cost of 20,872.18 baht, representing a statistically significant difference (p-value < 0.01). This aligns with a study by Kamol Kanyaprasit,[16] which found that spinal anesthesia was associated with three to four times higher costs than local anesthesia. However, patient satisfaction has no significant difference between the two groups.

Limitation

The significant limitations of the study were that it is a single-center retrospective study and the sample size was relatively small.

Conclusion

The study's findings indicate that inguinal hernia surgery can be effectively performed under local anesthesia, offering several advantages. Notably, there were fewer postoperative complications, reduced pain levels after 6 hours, and lower costs associated with local anesthesia. Although the surgery may take longer, patients can safely return home without requiring a hospital stay. These findings suggest surgeons may consider opting for local anesthesia over spinal anesthesia when performing inguinal hernia surgeries.

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Original Article

Survival and Treatment Outcomes of Resectable Cholangiocarcinoma: Initial Experience in Khon Kaen Hospital

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Abstract

Background: The most effective current treatment for cholangiocarcinoma is surgical resection. Khon Kaen Hospital receives a significant number of cholangiocarcinoma patients, and it is essential to analyze the treatment outcomes and survival to improve future treatment processes.

Methods: A retrospective study that analyzes the treatment outcomes and survival of cholangiocarcinoma patients who underwent surgery at Khon Kaen Hospital between October 2014 to September 2019. The study covers patient demographics, disease characteristics, surgical information, treatment outcomes, complications, and survival analysis.

Results: There were a total of 84 predominantly male patients with an average age of 63 years. Most patients had intrahepatic type and presented with abdominal pain and jaundice. The most common complication was wound infection, 14%, and the overall perioperative mortality rate was 8%. The perihilar type had the highest mortality rate. The median survival time was 16.8 months, with the intrahepatic type having the most prolonged survival (23.2 months), followed by distal type (16.5 months) and perihilar type (9.2 months). These differences were statistically significant (P-value < 0.01). Positive margins and lymph node involvement were significant factors associated with shorter survival times.

Conclusion: Surgical treatment of cholangiocarcinoma at Khon Kaen Hospital is generally safe, with complication and mortality rates comparable to other research studies. Key factors for long-term survival include achieving a negative microscopic margin (R0 resection) and the absence of lymph node involvement.

Keywords: Cholangiocarcinoma surgery

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Introduction

Currently, the incidence of bile duct cancer is increasing worldwide, accounting for approximately 3% of gastrointestinal cancers. Cholangiocarcinoma is highly prevalent in Thailand, especially in the northeastern region, with incidence rates of approximately 89.5 per 100,000 males and 35.5 per 100,000 females.[1] At present, Cholangiocarcinoma is categorized based on its location, namely, intrahepatic, perihilar, and distal cholangiocarcinoma. Most patients (60-70%) fall into the perihilar type category.[2,3] The most effective treatment for cholangiocarcinoma is surgical resection. This procedure has resulted in 5-year overall survival rates ranging from 10-20% for intrahepatic type, 10-40% for perihilar type, and 23-50% for distal type.[4-10] Median survival time ranging from 20-30 months for intrahepatic type, 12-24 months for perihilar type, and 24-36 months for distal type.[4-10] Surgical resection is a complex procedure associated with high morbidity, reaching up to 17-63%, and perioperative mortality 5-10%.[4-10] Khon Kaen Hospital, a major tertiary care center in the northeastern region of Thailand, plays a crucial role in treating. This situation prompted the researchers to analyze detailed treatment outcomes for cholangiocarcinoma patients at Khon Kaen Hospital. The study covers disease characteristics, patient demographics, surgical data, survival duration, complications, and in-hospital mortality rates. This analysis aims to serve as a foundation for future improvements in treatment and enhance patient outcomes.

Materials and Methods

This study is a descriptive retrospective study and survival analysis. The data was collected from 84 patients diagnosed with cholangiocarcinoma who underwent surgical treatment at the Department of Surgery, Khon Kaen Hospital, between October 2014 to September 2019. This data included patient characteristics, disease characteristics, surgical information, treatment outcomes, complications, and survival times. Analyze and summarize this data to produce research findings for dissemination to interested parties (Figure 1).

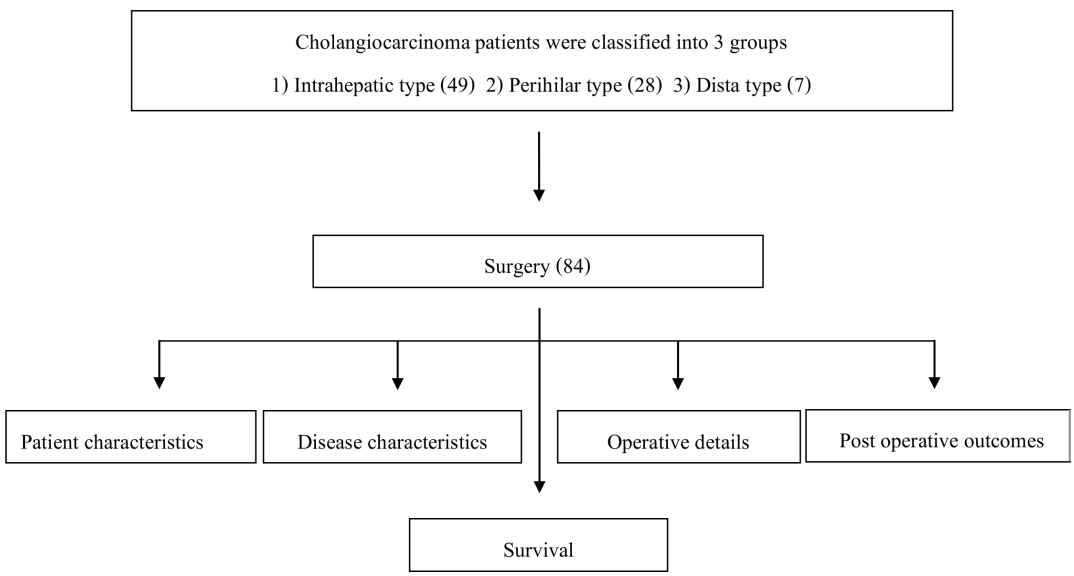

Figure 1

Results

Among patients with cholangiocarcinoma who received surgical treatment at the Department of Surgery, Khon Kaen Hospital, during the 5-year data collection period, a total of 84 cases were identified. The majority of these cases were found to be of the intrahepatic type 49 (58%), followed by the perihilar type 28 (33%), and finally the distal type 7 (8%). Most patients were male, with a male-to-female ratio of 7:3. The average age was 63 years (25-79). The average body mass index (BMI) was 22.2 (18.5 to 25.8).

The most common accounting presenting symptom among patients for 28 (33%) is abdominal pain. This is the predominant symptom in the overall patient population

and the primary symptom in the intrahepatic type. The second most common symptom, observed in 22 (26%), is jaundice, characterized by yellowing of the skin and eyes. This is the major symptom in the perihilar type and the distal type. There is a statistically significant difference between these two groups (*P*-value < 0.01).

The majority of patients had an American Society of Anesthesiologists (ASA) score of I, II 52 (61.9%) or III, IV 32 (38.1%). Regarding laboratory findings, levels of total bilirubin, liver enzymes (AST, ALT), alkaline phosphatase (ALP), and serum albumin (Alb) were found to be higher in patients with perihilar type and distal type compared to those with intrahepatic type. There was a statistically significant difference in these laboratory parameters among the different tumor locations ($p < 0.001$). By patient characteristics, presenting symptoms, and laboratory findings according to the location of bile duct cancer, the data is presented in Table 1.

Table 1 Patient characteristics and laboratory results by location.

Clinical characteristics	Overall (n = 84)	Intrahepatic (n = 49)	Perihilar (n = 28)	Distal (n = 7)	*P*-value
Male sex, n (%)	59 (70.2)	31 (63.3)	21 (75.0)	7 (100.0)	0.12
Age, Median (min:max)	63 (25:79)	64 (35:79)	60 (26:76)	58 (25:71)	0.02*
BMI, Mean ± SD	22.19 ± 3.64	21.95 ± 3.58	22.50 ± 3.54	22.64 ± 4.86	0.78
Smoking, n (%)	67 (79.8)	40 (81.6)	22 (78.6)	5 (71.4)	0.70
No underlying disease, n (%)	56 (66.7)	29 (59.2)	22 (78.6)	5 (71.4)	0.80
Clinical presentation, n (%)					< 0.001*
Abdominal pain	51 (60.7)	40 (81.6)	11 (39.3)	0 (0.0)	
Jaundice	22 (26.2)	0 (0.0)	16 (57.1)	6 (85.7)	
Weight loss	4 (4.8)	3 (6.1)	1 (3.6)	0 (0.0)	
Fever	3 (3.6)	2 (4.1)	0 (0.0)	1 (14.3)	
Previous abdominal surgery, n (%)	5 (6.0)	3 (6.1)	2 (7.1)	0 (0.0)	0.77
ASA Class, n (%)					0.76
I	9 (10.7)	6 (12.2)	3 (10.7)	0 (0.0)	
II	43 (51.2)	26 (53.1)	14 (50.0)	2 (42.0)	
III	31 (36.9)	17 (34.7)	10 (35.7)	3 (57.1)	
IV	1 (1.2)	0 (0.0)	1 (3.6)	0 (0.0)	
Laboratory information					
Bilirubin (Mean ± SD)	6.62 ± 10.97	0.88 ± 1.61	13.13 ± 14.03	10.70 ± 7.92	< 0.001*
Alkaline phosphatase (Mean ± SD)	207 ± 173.30	141.73 ± 92.38	255.58 ± 155.65	471.42 ± 332.80	< 0.001*
AST (Mean ± SD)	63.39 ± 63.82	41.59 ± 44.38	92.21 ± 80.97	100.71 ± 41.27	0.001*
ALT (Mean ± SD)	60.35 ± 72.27	37.79 ± 34.4	94.75 ± 107.27	80.71 ± 28.83	< 0.001*
Albumin (Mean ± SD)	4.10 ± 3.25	3.86 ± 0.49	4.50 ± 5.61	3.57 ± 8.11	< 0.001*

**P*-value less than 0.05 was statistically significant

From the study results presented in Table 2, it was found that nearly all patients who underwent surgical treatment had adenocarcinoma 81 (98.8%). Among these cases, the majority were classified as well-differentiated, representing 77 (91.7%). Larger tumor sizes > 2 centimeters were predominantly observed in the intrahepatic type 46 (93.9%), which was statistically significantly different from the perihilar and distal types ($p < 0.01$). Additionally, angiolymphatic invasion was observed in 25 (29.8%), and lymph node involvement was noted in 28 (33.3%).

In terms of surgical details, an average of 3.69 ± 3.12 lymph nodes were dissected during surgery. A negative microscopic margin (R0 resection) was achieved in 53 (63.1%). Notably, the likelihood of complete tumor resection was higher in the distal type than in the intrahepatic and perihilar types, with statistically significant differences ($p < 0.01$). In most cases, liver resection was performed in addition to bile duct resection during surgery, particularly in the perihilar type.

Table 2 Disease characteristics by location.

Disease characteristics	Overall (n = 84)	Intrahepatic (n = 49)	Perihilar (n = 28)	Distal (n = 7)	*P*-value
Tumor histology, n (%)					
Adenocarcinoma	83 (98.8)	49 (100.0)	27 (96.4)	7 (100.0)	0.41
Degree of differentiation, n (%)					
Well	77 (91.7)	5 (91.8)	26 (92.9)	6 (85.7)	0.72
Moderate	6 (7.1)	3 (6.1)	2 (7.1)	1 (14.3)	
Poor	1 (1.2)	1 (2)	0 (0.0)	0 (0.0)	
Tumor diameter (> 2 cm), n (%)	60 (71.4)	46 (93.9)	12 (42.9)	2 (28.6)	< 0.001*
Angiolymphatic invasion, n (%)	25 (29.8)	12 (24.5)	12 (42.9)	1 (14.3)	0.05
Negative microscopic margins, n (%)	53 (63.1)	37 (75.5)	10 (35.7)	6 (85.7)	0.001*
Lymph node involvement, n (%)	28 (33.3)	17 (34.7)	9 (32.1)	2 (28.5)	0.93
Number of retrieved lymph nodes (Mean ± SD)	3.69 ± 3.12	4.6 ± 3.18	2.21 ± 2.51	3.14 ± 2.91	0.004*

**P*-value less than 0.05 was statistically significant

Table 3 presents the surgical procedures and perioperative complications observed in all 84 patients. In the group of intrahepatic type, surgical treatment primarily involved anatomical resection of the liver and regional lymphadenectomy. For patients with perihilar type, the surgical approach included extrahepatic bile duct resection, which may also involve anatomical liver resection with or without caudate inclusion, along with regional lymphadenectomy. In the case of the distal type, the surgical procedure typically consisted of pancreaticoduodenectomy, extrahepatic bile duct resection, and regional lymphadenectomy.

The most common complications were wound infection 12 (14.3%), respiratory infection 9 (10.7%), postoperative liver failure 8 (9.5%), biliary leak 5 (5.9%), and pancreatic leak 1 (1.2%). When analyzed by groups, biliary leak was more frequently observed in the perihilar cholangiocarcinoma group. The average duration of surgery was 5 hours and 15 minutes, with an average blood loss of 1,071 milliliters. The overall perioperative mortality rate was 7 (8.3%), with a breakdown of 2 (4.1%) for intrahepatic type, 4 (14.3%) for perihilar type, and 1 (14.3%) for distal type. The main cause of mortality was respiratory infection, followed by postoperative liver failure.

Table 3 Postoperative complications, operative details, perioperative mortality, and median survival by location

Postoperative details	Overall (n = 84)	Intrahepatic (n = 49)	Perihilar (n = 28)	Distal (n = 7)	*P*-value
Wound infection, n (%)	12 (14.3)	8 (16.3)	4 (14.3)	0 (0.0)	
Biliary leak, n (%)	5 (5.9)	2 (4.1)	3 (10.7)	0 (0.0)	
Pancreatic leak, n (%)	1 (1.2)	0 (0.0)	0 (0)	1 (3.6)	
Sepsis, n (%)	3 (3.6)	3 (6.1)	0 (0.0)	0 (0.0)	
Respiratory, n (%)	9 (10.7)	6 (12.2)	3 (10.7)	0 (0.0)	
Multiorgan failure, n (%)	2 (2.4)	2 (4.1)	0 (0.0)	0 (0.0)	
Postoperative liver failure, n (%)	8 (9.5)	6 (12.2)	1 (3.6)	1 (14.3)	
Pulmonary embolism, n (%)	1 (1.2)	1 (2.0)	0 (0.0)	0 (0.0)	
IVC injury, n (%)	1 (1.2)	1 (2.0)	0 (0.0)	0 (0.0)	
Perioperative mortality, n (%)	7 (8.3)	2 (4.1)	4 (14.3)	1 (14.3)	0.21
Estimated blood loss (CC), (Mean ± SD)	1,071.59 ± 933.03	1,126.33 ± 982.87	964.89 ± 851.47	1,100 ± 975.11	0.77
Operative time (Min), (Mean ± SD)	315.12 ± 118.11	301.42 ± 108.91	311.85 ± 115.53	423 ± 150.35	0.03*
Median survival (month)	16.8	23.2	9.2	16.5	< 0.001*

**P*-value less than 0.05 was statistically significant

The study investigated overall survival duration in all cholangiocarcinoma patients who received surgical treatment. The overall median survival duration was found to be 16.8 months. When comparing median survival durations among different locations of cholangiocarcinoma, it was observed that the intrahepatic type had the highest median survival at 23.2 months, followed by the distal type at 16.5 months and the perihilar type at 9.2 months. These differences were statistically significant (p-value < 0.01), as shown in Figure 1.

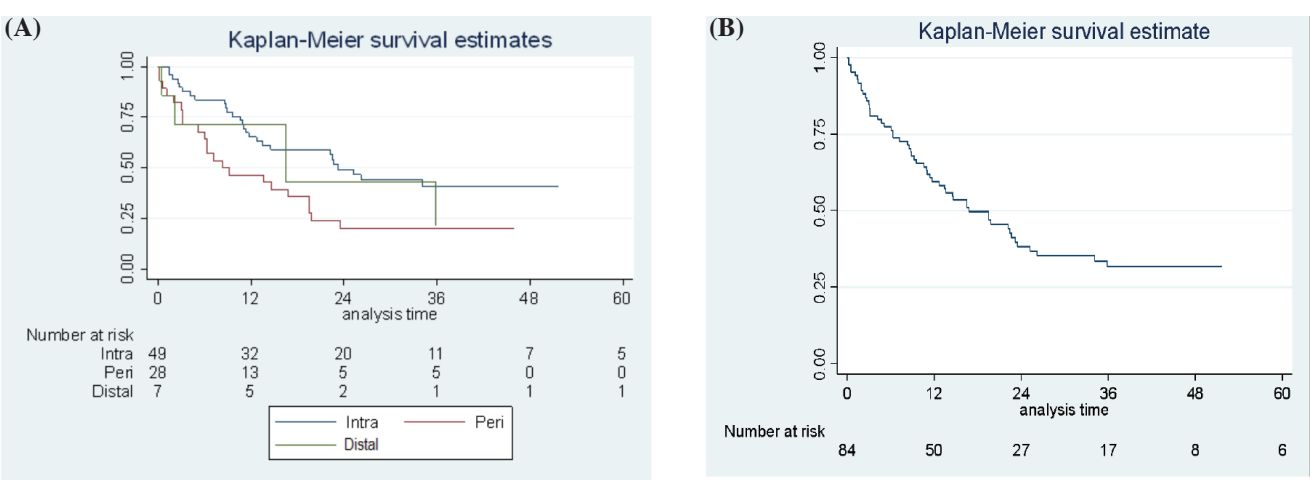

Figure 1 Overall survival for the entire group (A) and by tumor location (B)

The study also examined the impact of surgical outcomes, including positive surgical margins, lymph node involvement, tumor size, and degree of differentiation on survival outcomes. It was found that positive surgical margins and lymph node involvement had a significant impact on survival, with adjusted hazard ratios of 2.19 (95% CI 1.24-3.83) and 1.85 (95% CI 1.07-3.23), respectively, as shown in Figure 2 and Table 4.

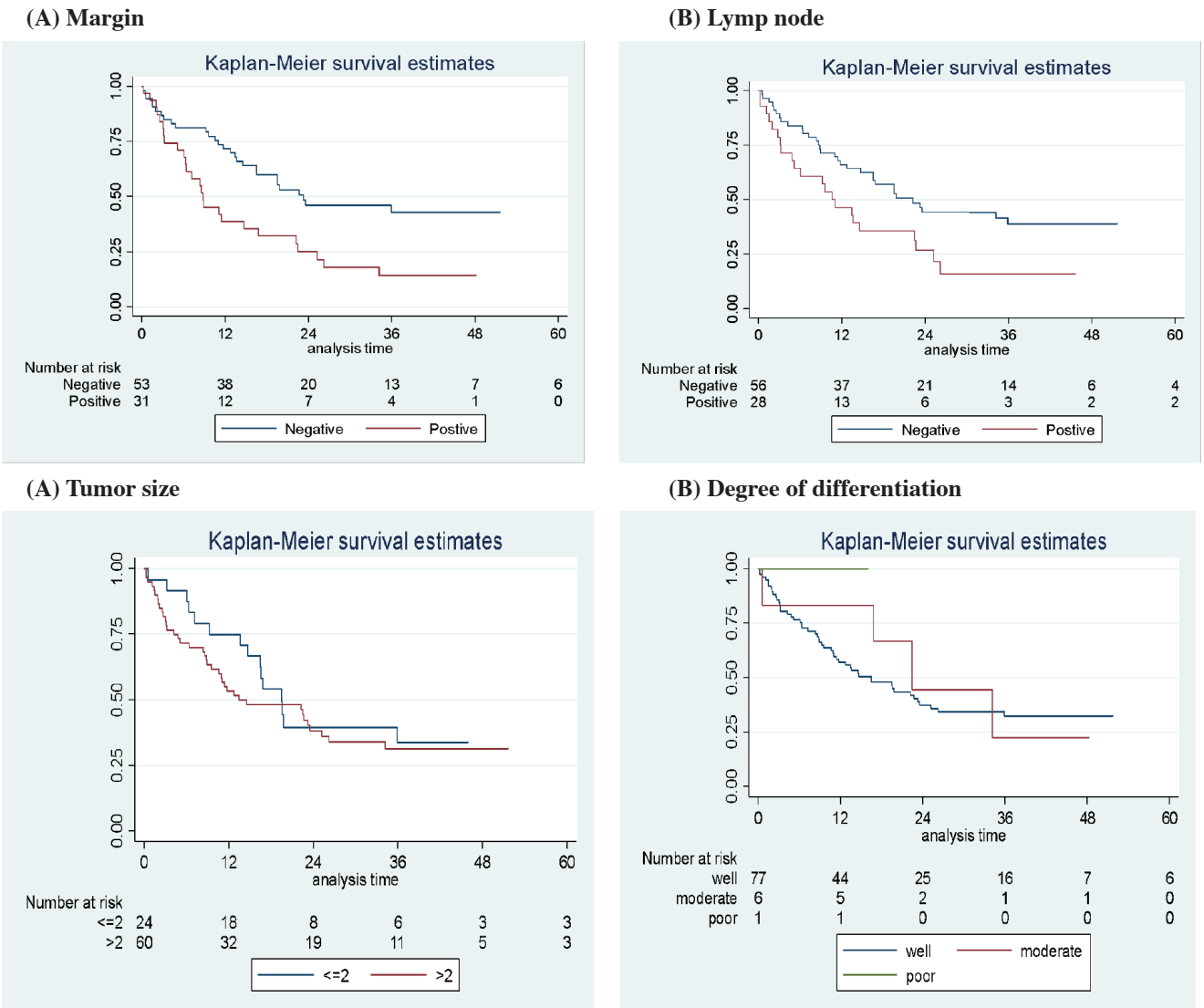

Figure 2 Survival by margin (A), lymph node (B), tumor size (C) and degree of differentiation (D)

Table 4 Factors predicting survival by tumor location

Factors	Overall		Intrahepatic		Perihilar		Distal	
	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted
Margin								
Negative	1	1	1	1	1	1	1	1
Positive	2.20 (1.29 - 3.77)*	2.19 (1.24 - 3.83)*	2.42 (1.22 - 5.23)*	1.94 (0.80 – 4.70)	1.51 (0.62 – 3.65)	3.74 (0.34 – 2.40)	5.47 (0.31 - 87.82)	NA
Lymph node								
Negative	1	1	1	1	1	1	1	1
Positive	1.90 (1.10 - 3.29)*	1.85 (1.07 - 3.23)*	2.97 (1.37 - 6.43)*	2.87 (1.25 - 6.58)*	2.29 (0.94 - 5.57)	3.74 (1.31 - 10.69)*	NA	NA
Tumor size								
≤ 2 cm	1	1	1	1	1	1	1	1
> 2 cm	1.23 (0.67 - 2.23)	1.24 (0.68 - 2.28)	NA	NA	1.71 (0.73 - 4.01)	2.90 (1.01 - 8.35)*	NA	NA
Differentiation								
Well	1	1	1	1	1	1	1	1
Moderate	0.87 (0.32 - 2.41)	0.55 (1.91 - 1.57)	0.81 (0.19 - 3.45)*	0.43 (0.09 - 2.07)	1.91 (0.44 - 8.37)	4.63 (0.79 - 26.99)	NA	NA
Poor	NA	NA	NA	NA	NA	NA	NA	NA

**P*-value less than 0.05 was statistically significant

Discussion

From the research study, a total of 84 cholangiocarcinoma patients who underwent surgery and had confirmed pathological specimens at Khon Kaen Hospital over a 5-year period, from 2014 to 2019, were included. These patients were categorized into three groups based on the location of the tumor: intrahepatic, perihilar, and distal cholangiocarcinoma.

It is noteworthy that most patients presented with abdominal pain and jaundice. In the clinical setting, perihilar type was observed most frequently. However, the proportion of patients in this study was different, with intrahepatic type being the most prevalent. This difference can be attributed to the higher likelihood of surgical treatment for the intrahepatic type compared to the perihilar type. This is because, from an anatomical perspective, the perihilar type is located in close proximity to critical structures and has a higher tendency to invade adjacent tissues, making it less amenable to surgical resection. Therefore, the opportunity for surgical treatment for the perihilar type is lower than for the intrahepatic type.

When statistically compared, the study observed that the group of perihilar type had the shortest overall survival time among the three groups: intrahepatic, perihilar, and distal type cholangiocarcinoma. This shorter survival duration in perihilar cholangiocarcinoma patients is significant and is attributed to various factors. Firstly, the negative margin achieved during surgery was 35.7%, the most limited in the perihilar type compared to the other two groups, 75.5% in the intrahepatic type and 85.7% in the distal type. This indicates that complete removal of cancerous tissue was less achievable in the perihilar type, which can negatively impact patient outcomes. Secondly, the higher incidence of angiolymphatic invasion in the perihilar type was 42.9% compared to the other two groups, 24.5% in the intrahepatic type and 14.1% in the distal type. Angiolymphatic invasion is a negative prognostic factor associated with a more aggressive disease course. Additionally, the study showed the presence of overall lymph node involvement at 33.3%, indicating that

cancer had spread to the lymph nodes during the surgical treatment. This lymph node involvement is associated with a worse prognosis and reduced survival time.

Overall, these findings highlight the complex nature of cholangiocarcinoma and the challenges associated with its treatment. The limited feasibility of achieving negative margins, the higher likelihood of lymph node involvement, and the presence of angiolymphatic invasion contribute to the shorter survival times observed in cholangiocarcinoma patients. These results are consistent with previous research, further emphasizing the importance of accurate prognostic factors in guiding treatment decisions for cholangiocarcinoma patients.

From the study, it is evident that the treatment of perihilar cholangiocarcinoma had the lowest rate of achieving negative margins when compared to intrahepatic and distal extrahepatic cholangiocarcinoma groups, requires a more extensive surgical approach involving the removal of liver tissue in addition to the tumor itself is attributed to the anatomical location of the tumor which is often situated close to critical structures and can easily spread to adjacent tissues and to achieve negative margins effectively. This extensive surgical procedure is associated with a higher risk of complications and mortality compared to intrahepatic and distal cholangiocarcinoma cases. As a result, complete tumor removal through surgery is more challenging in perihilar cholangiocarcinoma.

It is widely known that intrahepatic cholangiocarcinoma has a different epidemiology than extrahepatic cholangiocarcinoma. Our study observed that patients with intrahepatic cholangiocarcinoma had the best overall survival outcomes among the three groups, even though there was a lower rate of R0 resection and a higher incidence of metastasis to the lymph nodes compared to distal types. This finding is consistent with some previous research.[8,9]

The preoperative assessment of patients with cholangiocarcinoma has evolved significantly in recent years. The goal is to obtain the most accurate and detailed information to ensure precise surgical planning. Advanced imaging techniques are now commonly used in the evaluation process, including high-resolution computed tomography (CT) scans that can create three-dimensional reconstructions. Additionally, computerized tomography angiography (CTA) of the visceral organs and magnetic resonance cholangiopancreatography (MRCP) is employed to visualize the biliary tract and liver.[11]

Conclusion

The surgical treatment of cholangiocarcinoma at Khon Kaen Hospital has demonstrated favorable treatment outcomes, high safety levels, minimal complications, and a low mortality rate following surgery. These results align with the standards observed in other research studies. Key factors associated with long-term survival include achieving R0 resection and the absence of lymph node involvement. As a result, there is a strong focus on developing surgical techniques that optimize R0 resection and the early detection of patients who do not yet display signs of lymph node spread. Continuous research efforts in this direction are ongoing at Khon Kaen Hospital.

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Original Article

Diagnostic Efficacy of Bi-Parametric Versus Multiparametric Magnetic Resonance Imaging for Detection of Prostate Cancer in Thai Patients

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Abstract

Background: The bi-parametric MRI (bpMRI) was based on T2-weighted (T2W) imaging and functional sequence diffusion-weighted imaging (DWI). The multiparametric MRI (mpMRI) comprises bpMRI and dynamic contrast enhancement (DCE). However, the value of DCE in the detection of prostate cancer is still controversial. This study aimed to evaluate the diagnostic accuracy of bpMRI versus mpMRI for prostate cancer.

Methods: Retrospective analysis of 109 patients who underwent mpMRI with prostate biopsy from January 2015 to March 2021. The bpMRI included T2W, DWI, and the apparent diffusion coefficient (ADC) map, and DCE was added to the mpMRI with masked clinical and laboratory information. Two diagnostic radiologists interpreted both examinations separately. The performance, diagnostic test accuracy, and subgroup analysis were analyzed.

Results: Around one-third (31.2%) of 109 patients were positive malignancies. The diagnostic accuracy of bpMRI was less than mpMRI, especially in the PI-RADS 3 group. The intra-observer agreement between bpMRI and mpMRI was moderate. The inter-observer agreement between the two readers was minimal agreement. The mpMRI was more accurate in detecting prostate cancer than bpMRI, especially in the PI-RADS 3 group.

Conclusion: Our study showed that mpMRI was higher than bpMRI for detecting prostate cancer in both readers, especially diagnostic accuracy improvement in the PI-RADS 3 group.

Keywords: Prostate cancer, PCa, MRI prostate gland, bpMRI, mpMRI

Introduction

Prostate cancer was the 2nd most common cancer affecting men worldwide in 2020 and the fourth most common malignancy (9.2%) in the Thai male population.[1] Targeted prostate cancer screening was based on digital rectal examination (DRE) and serum PSA levels to reduce mortality.[2] Early diagnosis, targeted therapy, and accurate monitoring following the radical prostatectomy had a significant impact on the prognosis of these patients.[3]

MRI has been used for the non-invasive assessment of the prostate gland and surrounding structures. The standard biopsy did not cover all parts of the prostate; hence, the biopsy did not represent the whole gland in most cases.[4] The combination of diffuse tensor imaging (DTI) and dynamic contrast enhancement (DCE) had significantly better accuracy in prostate cancer diagnosis than either technique alone[5] before transrectal ultrasound-guided biopsies.[6] Diffusion-weighted imaging (DWI) and apparent diffusion coefficient (ADC)

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map imaging sequences could improve both qualitative and quantitative evaluation of prostate cancer.[7-8] Moreover, Gadolinium contrast administration helped detect prostate cancer.[9-11]

Normal anatomy of the prostate gland, from superior to inferior, consisted of the base (just below the urinary bladder), the mid-gland, and the apex. It was divided into four histological zones including: 1) The anterior fibromuscular stroma (AFS) contained no glandular tissue; 2) The transitional zone (TZ) contained 5% of the glandular tissue; 3) The central zone (CZ); contained about 20% of the glandular tissue and 4) The peripheral zone (PZ) contained 70-80% of the glandular tissue. Approximately 70-75 of prostate cancer originated in the PZ and 20-30% in the TZ.[12-14]

The overall objective of the revised Prostate Imaging Reporting and Data System (PI-RADS v2.1) was to improve patient outcomes, including detection, localization, characterization, and risk stratification in patients with suspected cancer in the treatment of naive prostate glands.[6] Bi-parametric MRI (bpMRI) protocol based on T2-weighted (T2W) images and the functional sequences DWI. Multiparametric MRI (mpMRI) based on T2W images, DWI, and DCE functional sequences. However, the value of mpMRI in the detection of prostate cancer was still controversial. Some studies showed that combining DCE with T2W images and DWI did not significantly improve the diagnostic accuracy of prostate cancer.[7] There were many advantages to using bpMRI rather than mpMRI for the diagnosis of prostate cancer; mpMRI had a longer scan time, needed IV gadolinium contrast, more cost, risk for contrast complications, and limitations in poor renal function patients.[2,7-8] Moreover, bpMRI prostate protocol was more feasible for prostate cancer detection than mpMRI protocol,[3] with no difference in diagnostic performance.[2-4,7-8,15-17]

Our study aimed to evaluate the diagnostic accuracy of bpMRI versus mpMRI for prostate cancer patients.

Materials and Methods

Ethical Consideration

A retrospective descriptive diagnostic study was conducted at a university-based tertiary referral center in Thailand. The study was conducted following the Declaration of Helsinki, and the Ethics Committee approved the protocol for Human Research.

Study Population

The MRIs of the prostate gland of suspected prostate cancer patients from January 2015 to March 2021 were retrospectively reviewed.

Inclusion criteria

1. Patients who were suspected of prostatic cancer.
2. Patients who underwent MRI of the prostate gland.
3. Patients who underwent prostatic biopsy with pathology confirmed.

Exclusion criteria

Patients who were treated before undergoing an MRI of the prostate gland, including surgery, radiation therapy, chemotherapy, or hormonal therapy.

Hardware and Data Acquisition

All examinations were performed in a 3T MRI scanner (Achieva dStream, Philips Healthcare) or 1.5T MRI scanner (Aera, Siemens AG 2012) without an endorectal coil.

All mpMRI included tri-planar (axial, sagittal, and coronal) views, according to European Society of Urogenital Radiology (ESUR) guidelines, involved T2W turbo spin-echo images, DWI in the axial plane with multiple b-values (b = 0, 100, 800, 1000, 1500) where b = 1,000 or 1,500 s/mm^2 was used for visual assessment and the remaining three b-values in the calculation of the ADC map and the DCE, T1-weighted (T1W) images in the axial plane.

Image interpretation

The image interpretation was independently done by two advanced body imaging radiologists (one was an experienced uro-genitourinary radiologist) with masked patient information. First, all MRI images were classified index lesions with a bi-parametric diagnostic approach involving T2W, DWI, and ADC-map images, according to the PI-RADS v2.1, whereas the DCE sequence was ignored. Second, DCE sequences were included in the same MRI images, and the whole mpMRI examination was re-classified according to PI-RADS v2.1. Diagnostic accuracy, tumor detection rate, and bpMRI and mpMRI sub-group analysis were compared. The study also categorized the PI-RADS scoring system as negative (PI-RADS 1-2), intermediate (PI-RADS 3), and positive (PI-RADS 4-5).

The pathological result was categorized as benign and malignant based on the Gleason score. Malignancy was significant PCa (Gleason ≥ 6, at least 3+3).

Statistical analysis

Categorical variables were demonstrated as numbers (percentages). Continuous variables were demonstrated as mean (standard deviation, SD) or median (interquartile range, IQR). Comparison of categorical and continuous variables of subgroups was performed using Fisher's exact test and/or Chi-square test, as appropriate. A *p*-value < 0.05 was considered statistically significant.

Sensitivity and specificity, likelihood ratio (LR), test yield (YD), and accuracy were calculated for both readers and both methods.

Results

A total of 400 MRI examinations of patients between January 2015 and March 2021 were retrospectively reviewed; 291 studies were excluded due to no clinical suspicion of prostate cancer, incomplete data, and prior treatments (including surgical, radiation, and hormonal therapy). Thus, 109 MRI studies met inclusion criteria and were included in analyses.

The patient's ages ranged from 50-89 years (mean ± SD, 66.8 ± 7.18), 34 of 109 patients (31.2%) were positive for PCa. The median of serum PSA levels was 10.59 ng/mL (IQR = 6.76 - 15.0), and the median of prostate volume was 39.62 cm3 (IQR = 19.81 - 63.49). There was no significant difference in serum PSA levels between benign and malignancy groups ($p = 0.073$). (Table 1).

A significantly larger proportion of cancer occurred in the peripheral zone (p = 0.001). The tumor in the transitional zone was not significantly different between the different PI-RADS groups (Table 2).

Table 1 Demographic and clinical data of the study population

Characteristic	Patients (n = 109)	*p*-value
Age (years)		
Mean (SD)	66.87 (7.18)	0.989
Minimum-Maximum	50.8-89.7	
Serum PSA levels (ng/mL)		
Median (IQR)	10.59 (6.76-15.9)	0.725
Serum PSA levels (ng/mL), median (IQR)		0.073
Benign	10.29 (6.49-14.90)	
Malignant	11.78 (9.11-21.95)	
Prostate gland volume (cm^3)		
Median (IQR)	39.62 (19.81-63.48)	0.843
Biopsy results, n (%)		
Benign	75 (68.8)	
Malignant	34 (31.2)	

Table 2 The location of the lesion with positive PCa

Location	Benign	Malignant	Total (n = 109)	*p*-value
Right lobe	34	14	48	0.809
Left lobe	35	18	53	0.807
Both lobes	6	2	8	0.873
Peripheral zone	30	25	55	0.001*
Transitional zone	45	9	54	0.2
Apex	20	8	8	0.650
Mid-gland	46	21	67	0.492
Base	7	1	2	0.539

*Statistical significance

There was a significant increase in the number of prostate cancers among the higher PI-RADS groups. The difference was significant in both bpMRI and mpMRI for both readers. The mpMRI showed less cancer in the intermediate group and more in the positive group than in the bpMRI (Table 3).

Table 3 Assessment of the categorized PI-RADS scoring system from both readers

PI-RADS score group	Reader 1				Reader 2			
	bpMRI		mpMRI		bpMRI		mpMRI	
	Benign	Malignant	Benign	Malignant	Benign	Malignant	Benign	Malignant
Negative	6	0	5	0	35	4	34	1
Intermediate	35	6	23	3	12	7	11	3
Positive	34	28	47	31	28	23	30	30

The sensitivity and specificity between bpMRI and mpMRI were similar. However, these parameters were quite different between both readers. The mpMRI resulted in a higher positive, negative, and overall test yield and slightly higher accuracy than bpMRI (Table 4).

Table 4 The accuracy of bpMRI and mpMRI from both readers.

Parameters	Reader 1		Reader 2	
	bpMRI	mpMRI	bpMRI	mpMRI
Sensitivity	1	1	0.852	0.968
Specificity	0.15	0.096	0.555	0.531
LR+	1.176	1.106	1.916	2.064
LR-	0	0	0.556	0.53
LR+-	0.378	0.287	1.287	0.602
Overall test yield	0.623	0.761	0.826	0.872
YD+	0.823	0.912	0.794	0.912
YD-	0.533	0.693	0.84	0.853
Accuracy	0.312	0.330	0.532	0.587

Intra-observer agreement between bpMRI and mpMRI was moderate; Cohen Kappa = 0.707 (reader 1) versus Kappa = 0.682 (reader 2). Inter-observer agreement (same and different modalities) was minimal (Cohen Kappa ranged from 0.245 to 0.335). The inter-observer agreement was weak for PIRADS 4-5 lesions (Cohen Kappa ranged from 0.411 to 0.582).

Discussion

The study found no significant difference in serum PSA levels between benign and malignant patients. Nevertheless, serum PSA levels and the number of patients were significantly increased in PI-RADS 5 group patients in both bpMRI and mpMRI of both readers, which were concordant with the high-risk prostatic cancer group and represented locally advanced prostatic cancer.

After subgroup analysis correlation of PI-RADS score and tumor grade group, the study showed the tumor in higher pathology grade groups (grade 3-5) was found more frequently in PI-RADS 4-5 groups in both readers. A higher PI-RADS score helped predict a higher Gleason score, indicating clinically significant PCa and poor prog-

nostic factors.[18] Not only does the PI-RADS score helps predict the Gleason score, but it also reduces the number of unnecessary biopsies while maintaining a high rate of diagnosis of clinically significant prostate cancers.[19]

The number of lesions in transitional zone cancers was not significantly different between the different PI-RADS groups, which could be from difficulty in achieving high accuracy in the diagnosis of PCa of the TZ due to the described stromal tissue in the TZ, similar to the previous study,[20] even mpMRI using the combination of sequences had the potential to improve the accuracy of TZ cancer detection and staging.[21-22]

Similar to another study,[23] both readers showed that mpMRI could improve diagnostic accuracy. Moreover, mpMRI resulted in a lower likelihood of intermediate results (PIRADS 3) from both readers, higher positive-, negative-, overall test yield, and slightly higher accuracy than bpMRI. The PROMIS study showed that incorporating mpMRI into the initial test before prostate biopsy reduced unnecessary biopsies, improved detection, and increased the cost-effectiveness of the prostate cancer diagnostic and therapeutic pathway.[24]

The interpretation of prostate MRI was operator-dependent, as was evidenced by the noticeable difference in the accuracy between both readers. The agreement between bpMRI and mpMRI was substantial for both readers. However, the agreement between the two readers was only minimal.

The limitation of this study was a retrospective design in which confounding factors may be presented. In addition, some pitfalls confounding prostate MRI interpretation included motion artifact, history of previous prostate biopsy, full urinary bladder, bowel artifact, and infection process such as a prostatic abscess. Furthermore, normal anatomic structures mimicked focal lesions such as stromal BPH nodules and technical challenges like anatomical distortion of high-b-value diffusion-weighted images that might lower the sensitivity for tumor detection.

Conclusion

Our study showed that mpMRI was higher than bpMRI for detecting prostate cancer in both readers, especially diagnostic accuracy improvement in the PI-RADS 3 group.

List of Abbreviations

ADC = Apparent diffusion coefficient; AFS = Anterior fibromuscular stroma
bpMRI = bi-parametric MRI; CZ = Central zone
DCE = Dynamic contrast enhancement; DRE = Digital rectal examination
DTI = Diffuse tensor imaging; DWI = Diffusion-weighted imaging
ESUR = European Society of Urogenital Radiology; IQR = Interquartile range
LR = Likelihood ratio; MRI = Magnetic Resonance Imaging; mpMRI = multiparametric MRI
PCa = Prostatic cancer; PI-RADS = Prostate Imaging Reporting and Data System
PSA = Prostatic Specific Antigen; PZ = Peripheral zone; SD = Standard deviation
T1W = T1-weighted; T2W = T2-weighted; TRUS = Transrectal ultrasound
TZ = Transition Zone; YD = Test yield

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Case Report

The Outcome of Non-Operative Treatment Following Complex Pancreaticoduodenal Injury: A Case Report

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Abstract Complex pancreaticoduodenal injury is an uncommon event that is often difficult to diagnose at an early stage. After abdominal trauma, the surgeon must always be aware of the possibility of pancreaticoduodenal trauma due to the complications associated with missed pancreaticoduodenal injuries. Due to its retroperitoneal position, associated organ and vascular injuries are almost always present, which, along with frequent extra-abdominal injuries, explain the high morbidity and mortality. A high index of suspicion, mechanism of injury, and early identification are key to the final outcome. This study aimed to present a concise description of the outcome of nonoperative management after a complex pancreaticoduodenal injury and the analysis of pancreaticoduodenal-specific complications and morbidity in these patients.

Keywords: Complex pancreaticoduodenal injury, Pancreatic trauma, Duodenal injury, Blunt abdominal trauma

Introduction

Complex pancreaticoduodenal (PD) injuries after blunt abdominal trauma are rare due to their retroperitoneal location, with rates of 1–5%. In addition, if there are no specific physical signs or indicators, diagnosis can be delayed. Timely diagnosis and treatment are crucial since the mortality associated with this condition is 7.1–12.4% due to the difficulty in management.[1] Several factors contribute to a poor prognosis, such as the presence of coexisting injuries to other abdominal organs and the high risk for postoperative complications, including traumatic pancreatitis, pancreatic and duodenal fistulas, diffuse peritonitis, bile leakage, abdominal abscesses, and pancreatic pseudocysts.[2] To evaluate the diagnosis and management of high-grade PD trauma in more detail, we reported the outcome after conservative treatment in one patient. We emphasized the need for imminent surgery in such an acute setting and described one possible surgical option in view of the wide variability regarding the management of such injuries.

Case presentation

A 57-year-old male patient was brought into the Phrapokklao Hospital Emergency Room with blunt abdominal trauma after being involved in a motor vehicle crash. The patient did not have any contributory family, psycho-social, or drug histories.

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On admission, he was fully conscious but anxious, with saturation at 99% oxygen per face mask. He was tachycardic (pulse = 110 bpm). His abdomen was mildly distended with localized tenderness at the right upper quadrant (Figure 1). No other external injuries were noted. A full blood count showed a white cell count of 3, 65/mm^3, a hemoglobin of 13, 5 g/dl, and a platelet count of 250 × 106. A chest x-ray was unremarkable. Extended Focused Abdominal Sonography (eFAST) for trauma demonstrated the presence of free fluid in the hepato-renal region.

After initial fluid resuscitation, an emergency imaging study was conducted. A contrast-enhanced CT scan of the abdomen showed a massive pancreatic head hematoma, a laceration of the liver segment 4B, gallbladder distension, swelling around the hepatoduodenal ligament, and minimal free fluid in the sub-hepatic area (Figure 2).

This patient was admitted to the trauma service and was initially managed with nonoperative treatment. After being admitted to the hospital for 48 hours following a period of rest, the patient had abnormal liver function test results, indicating Hyperbilirubinemia, which raised suspicion about bile duct and pancreatic duct injury. Further radiological examination was conducted with MRCP, which revealed an abrupt change in the caliber of the mid-part of the common bile duct and pancreatic duct (Figure 3). However, the patient's vital signs were stable, and there was no fever. After the abdominal pain had subsided, the patient had a good appetite. Therefore, the treatment plan was non-surgical, and the patient began a diet on Admission day 3. The patient was able to eat without experiencing abdominal pain and was discharged on Day 7 without any reported morbidity. A follow-up plan was made to assess the bile duct and pancreatic duct injuries using MRCP again in Week 4 after the injury as an outpatient case.

Figure 1 Showed a mild distended abdomen

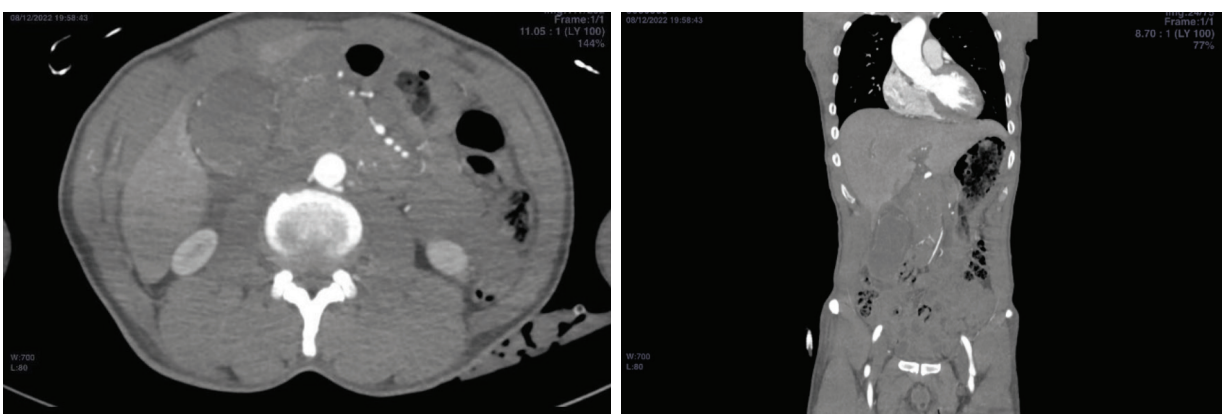

Figure 2 Axial CT abdomen initially

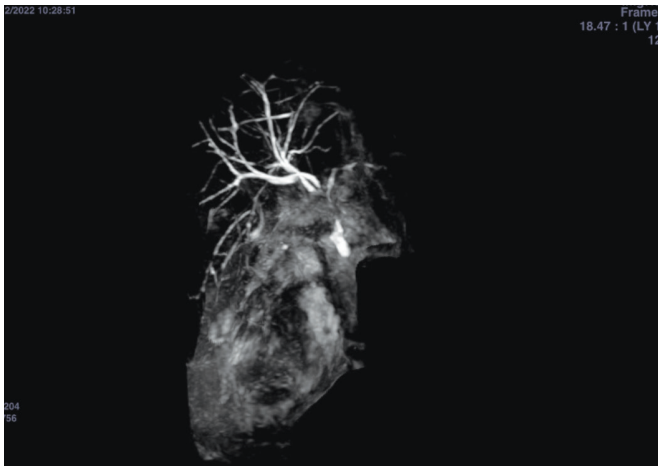

Figure 3 MRCP revealed an abrupt change in the caliber of the common bile duct

On day 28 after the injury, the MRCP results showed a decreased size of the duodenal hematoma and hematoma around the hepatoduodenal ligament, the irregular wall of the gallbladder. In addition, the continuity of the distal common bile duct and proximal pancreatic duct could not be identified (Figure 4). Based on the MRCP findings, it was suspected that there had been bile duct and pancreatic duct injury. Therefore, the treatment plan was to conduct an Endoscopic Retrograde Cholangiopancreatography (ERCP) along with biliary and pancreatic duct stent placement in the urgency or elective era due to normal physiologic patient status.

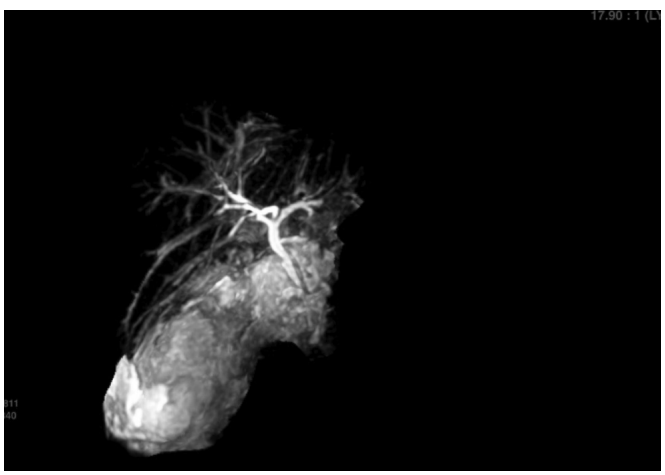

Figure 4 MRCP at day 28 after injury

The patient came to the Emergency Department before their scheduled appointment for ERCP on Day 31 after injury because of symptoms of increased abdominal girth, decreased appetite, and nausea, but with no fever or jaundice. Based on the patient's symptoms, there was suspicion of small bowel obstruction, so a CT scan of the abdomen was performed. The CT scan showed massive intraperitoneal free fluid, but there was no extraluminal free air or signs of gut obstruction (Figure 5). Based on the patient's symptoms and imaging, there was suspicion of biliary or pancreatic ascites, which was confirmed by the patient's latest MRCP on Day 28 after injury and which showed combined bilio-pancreatic duct injuries.

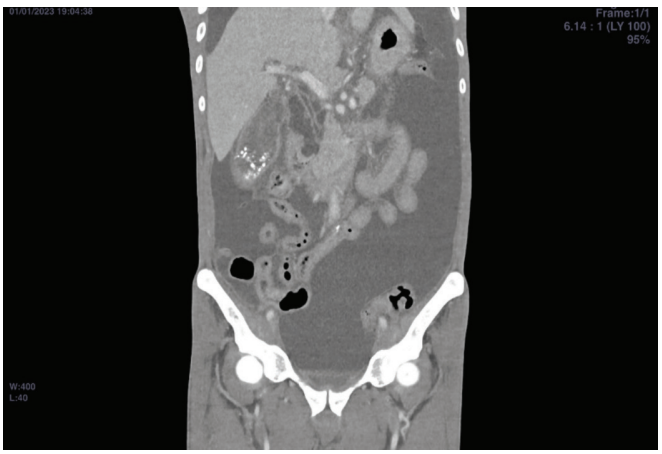

Figure 5 CT scan showed massive intraperitoneal free fluid

The treatment plan was a combined endoscopic and interventional approach under general anesthesia. After the procedure, percutaneous abdominal fluid drainage (PCD) was accessed using ultrasound guidance, and the fluid was found to be bile fluid. There were no immediate complications, and an ERCP was subsequently performed. Intraoperative findings showed no duodenal hematoma or perforation, but an abrupt caliber of the mid-common bile duct was found. It was, therefore, not possible to cannulate the pancreatic duct. A standard endoscopic sphincterotomy was performed, and a cholangiogram showed free contrast leakage from the lateral part of the mid-common bile duct, which was impeded by inserting a 10-F transpapillary biliary stent (Figure 6).

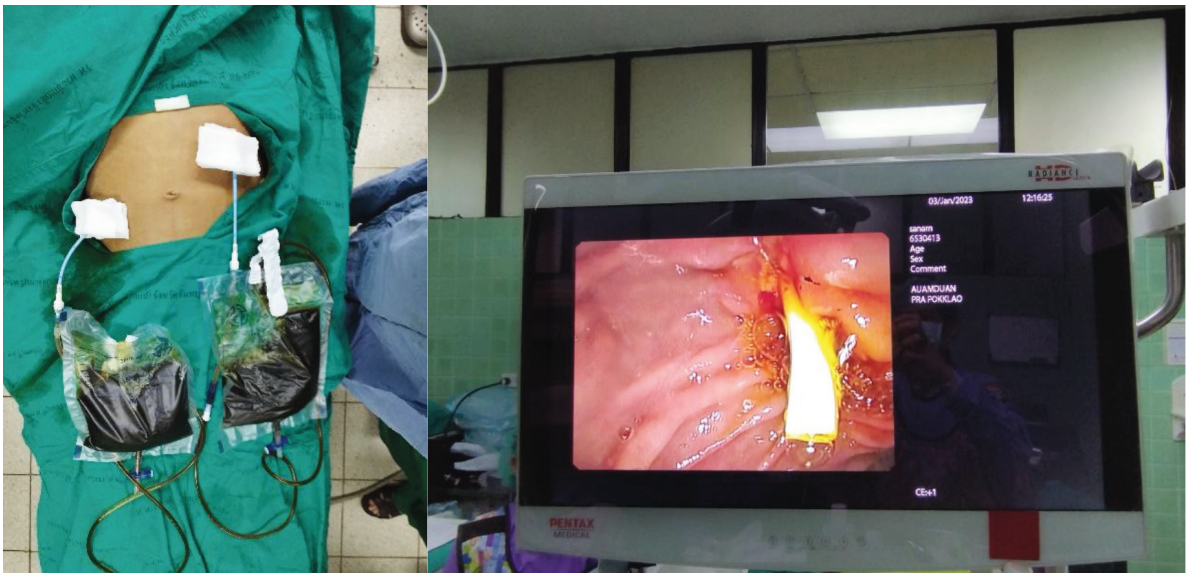

Figure 6 Showed external drainage and ERC with stent insertion

The patient was extubated and able to start a diet without abdominal pain or fever 36 hours post-operation. However, the patient later developed generalized abdominal pain and a high fever, and upon physical examination, generalized peritonitis was found. Suspecting complications or adverse events, an emergency CT scan of the abdomen was performed, which revealed a new onset right retroperitoneal fluid collection with an internal air bubble, but there was no intraperitoneal free air. Based on the symptoms and imaging, it was suspected that there may be continuous leakage from the extrahepatic biliary tree, and therefore, the patient had to undergo open abdominal surgery.

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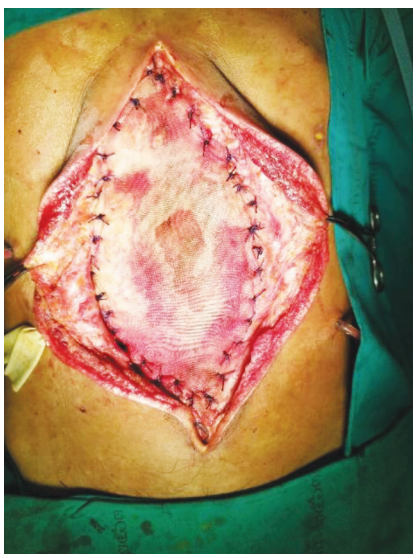

Figure 7 Abdominal closure with vicryl mesh

On Post-operative day 3, there was a problem with the vacuum-assisted control (VAC) dressing and Penrose drain because they contained small bowel contents. Blood chemistry fluid amylase revealed a small bowel leakage with the development of an entero-atmospheric fistula. However, since the contents leaked out at only 800-1000 ml/day and the patient's vital signs were stable without fever or abdominal pain, enteral nutrition was administered at full capacity, and conservative treatment was planned for the entero-atmospheric fistula (Figure 8).

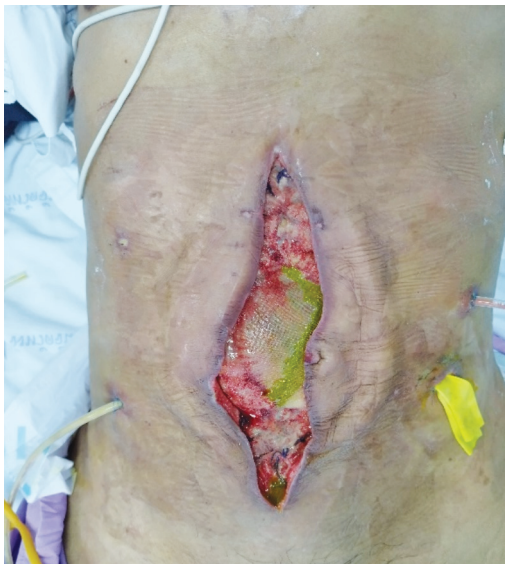

Figure 8 Entero-atmospheric fistula

On postoperative day 48, all drains and catheters were removed, and the VAC dressing on the abdominal wound was healing well, showing granulation tissue formation. There was no further content leak from the abdominal wound, and the patient could eat normally and gain weight. The patient was discharged from the hospital with plans for long-term follow-up and delayed abdominal wall reconstruction (Figure 9).

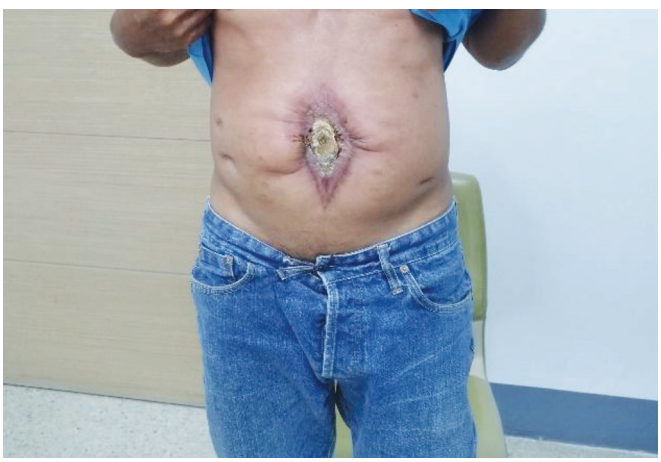

Figure 9 Patient during follow-up

Discussion

The treatment of pancreaticoduodenal injuries remains a great challenge for trauma surgeons due to the following: the relative rarity of the cases, the lack of reliable and accurate diagnostic methods, and the diagnostic methods being broadly time-dependent; the possibility to consider non-operative management; the variability of the lesions; and the frequent association with other lesions that can immediately be lethal, making it difficult to achieve good management skills and to increase suitable experiences in this field, as well as to achieve standardization of appropriate guidelines. They reportedly constitute about 2% of all blunt abdominal trauma.[3] The morbidity and mortality associated with pancreatic and duodenal trauma is high. There are reported mortalities of up to 30% in patients with blunt pancreatic trauma and up to 25% in patients with duodenal injuries. Early mortality is usually due to severe hemorrhaging from associated vascular injuries and multiple coexisting injuries. Severe anterior-posterior trauma, such as handlebar compressions, deceleration traumas, and seatbelt injuries, compresses these organs against the spine. Early diagnosis is crucial because a delay of even 24 hours can increase the risk of death by 4-fold. Common complications of duodenal and pancreatic injuries include pancreatitis, pseudocysts, fistulas, intra-abdominal abscesses, and bowel anastomosis breakdown, which can lead to sepsis and multi-organ failure.

Our report also described a significant number of IV injuries. This suggests that even higher-grade pancreaticoduodenal injuries may be clinically silent (pancreatic lucid interval) in the initial month after trauma and may present themselves later with growing biliary ascites. Also, since patients remained clinically and hemodynamically stable, further investigations were planned. CT is the most commonly used diagnostic modality for suspected pancreaticoduodenal trauma and its complications. CT reportedly has variable sensitivity (65%-80%) and specificity for detecting pancreatic trauma. CT is not a very sensitive test for pancreatic ductal injury. Specific signs of pancreatic injury included laceration, transection, focal pancreatic enlargement, and inhomogeneous enhancement. Fluid collections, like hematomas and

pseudocysts, were seen communicating with the pancreas at the site of laceration or transection. Nonspecific signs included peripancreatic fat stranding, peripancreatic fluid collections, fluid between the pancreas and splenic vein, hemorrhage, thickened left anterior pararenal fascia, and associated injuries to adjacent structures (15). The pancreas may appear normal in 20% to 40% of the patients when CT is performed within 12 hours after trauma because pancreatic injuries may produce little change in the density, which may not be detectable. This is likely due to obscuration of the laceration plane, hemorrhage, and close apposition of the pancreatic fragments. On repeat scanning at 12 to 24 h, an abnormality, which was initially ambiguous or subtle, becomes more evident. Findings become more radiologically apparent over time with the development of post-traumatic pancreatitis, edema, leakage of pancreatic enzymes, and the subsequent autodigestion of the surrounding parenchyma. The inability to detect early pancreatic trauma with CT may not be a limitation of CT technology but, instead, reflects the evolving nature of pancreatic trauma. An initial pancreatic contusion can progress to subsequent pancreatic transection with progressive autodigestion of the pancreatic gland. Serum Amylase Raised serum amylase can be useful in diagnosis. Still, there is a poor correlation between raised amylase and pancreatic trauma because amylase may be elevated in injuries to the salivary gland, in duodenal trauma, in hepatic trauma, and in injuries to the head and face, as well as in intoxicated patients. Almost one-third of patients may have a normal serum amylase at initial presentation despite pancreatic transection. A raised amylase level after blunt pancreatic trauma is time-dependent. Meanwhile, a persistently elevated or rising amylase level is a more reliable indicator of pancreatic trauma, but it does not indicate the severity of the injury. All our patients had elevated amylase levels, which probably reflects the late presentation and the evolved pancreatic injury.

The management and outcome of delayed pancreaticoduodenal injury patients were presented to us at an average of 4 weeks after the blunt trauma. Patients were initially managed with fluid resuscitation, antibiotics, and hyperalimentation when required. None of the patients had been hemodynamically critical on presentation to us. Patients complained of abdominal discomfort, nausea, and obstipation, which could be attributed to either fluid collections (sterile/infected) or gut obstruction.

Our results indicated that most patients could be managed non-surgically by drain placement into the fluid collections. An endoscopic or surgical drainage procedure could manage those who presented with biliary ascites. The morbidity rate was 35.4 % in the non-operative group and included pancreatitis, pancreatic abscesses, and recurrent pancreatic fistulas. ERCP with biliary stenting was needed in three patients who had persistent/recurrent pancreatic fistulas that were non-respondent to conservative measures. Trans-papillary stents can reduce the leaking of pancreatic fluid and bile leakage by bridging the disruption, or they can reduce the pressure of the pancreatic duct by allowing preferential flow through the stent into the pancreatic sphincter. A trial of Octreotide is generally given to control a high output (> 500 ml/day) pancreaticoduodenal fistula. There was an enteroatmospheric fistula in the surgically managed patients. No mortality was reported. There is a consensus that stable patients with low-grade pancreaticoduodenal injuries without pancreatic ductal injury (Grade I and Grade II) can be successfully and conservatively managed with low morbidity (< 20%) and mortality. Surgical treatments are mostly recommended for high-grade injuries with main pancreatic duct disruption (Grades III, IV, and V). For Grade III injuries, distal pancreatectomy with splenectomy is the standard surgery of choice. If the injury occurs at the neck, a pancreatico-jejunostomy may be done as an alternative. For Grade IV injuries, pancreatic drainage is recommended for damage control surgery. For pancreatic injury Grade V, treatment options vary from drainage to a single or two-stage pancreaticoduodenectomy.

Diagnostic delays and main pancreatic duct leaks are associated with increased morbidity and mortality. Early surgical management is associated with decreased morbidity and length of hospital stay, particularly for those injuries to the body and tail of the pancreas. In a study of 39 high-grade pancreatic injuries (Grades III and IV), patients who had received conservative treatments were observed to require longer hospitalizations and more days of total parenteral nutrition, as well as a greater incidence of complications. Conservative management of high-grade injuries is a topic of controversy. In recent years, there have been increasing numbers of publications describing the conservative management of high-grade pancreatic injuries with successful outcomes.

Hamidian et al. compared 39 patients with major ductal injuries undergoing surgical management with 12 patients who were undergoing conservative management. They concluded that both operative and non-operative management of major-grade blunt pancreatic injuries was acceptable, depending on the clinical condition, with similar complication rates. Morbidity remained high with non-operative management. However, the majority of the complications could be managed non-operatively. In hemodynamically stable patients, a controlled leak walled off as a pseudocyst, absent of associated organ injuries and absent of pancreatic necrosis, predicts a higher success rate for the non-operative strategy of high-grade pancreatic injuries. Koganti et al. have studied 34 patients with Grade III/IV trauma, of which 26 were initially under conservative management. Ten of them could be successfully managed without an operation, and based on multivariate logistic regression, the presence of necrosis and associated organ injury predicted the failure of conservative management. The development of a pseudocyst was associated with the success of non-operative treatment. They concluded that non-operative measures should be attempted in a select group of Grade III and Grade IV blunt pancreatic trauma patients, who were hemodynamically stable with a controlled leak that had been walled off as a pseudocyst and were without any associated organ injuries and pancreatic necrosis.

Our study also supported the feasibility of conservative management in patients with high-grade (III and IV) pancreaticoduodenal injuries who remained hemodynamically stable. In our patients, late complications were managed either with radiological drainage or surgical drainage. There was significant morbidity but no mortality. Morbidity was significantly less in those patients who had developed a pseudocyst. The interpretation of this report was limited due to its case report and the limited sample size. Our study of patients did not represent the complete spectrum of pancreaticoduodenal injuries, especially the more severe injuries involving hemodynamically unstable patients.

Conclusions

The overall mortality was comparable with the figures found in the literature worldwide. Adequate exploration of the pancreas and duodenum and conservative operative management are recommended when possible.

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Surgical Technique

Comparative Analysis of Balloon Tract Dilator and Metal Telescopic Dilators for Percutaneous Nephrolithotomy in Thai Patient Population

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Abstract

Background: Balloon dilators for percutaneous nephrolithotomy (PCNL) have been adopted in various countries worldwide. However, its utilization remains limited in Thailand due to the equipment cost and the country's higher morbidity and complexity of renal stones. We performed a comparative study between the outcomes of balloon dilators (BD) and the commonly used metal telescopic dilators (MTDs) in Thai patients who underwent PCNL.

Methods: We conducted a retrospective review of 199 patients who underwent PCNL between Jan 2011 and July 2022. We excluded patients with risk for bleeding and active infection from our study. 144 patients were recruited in our study: 74 patients in the MTD group and 70 patients in the BD group. The success rate and complication of both methods of dilation were compared. Continuous demographic data was compared with an independent t-test. A generalized linear model was applied to assess the multivariable analysis's mean differences and risk differences.

Results: Demographic data of patients in both groups were not significantly different in size of stone, age, and history of kidney surgery. The success rate of dilatation was 95.5% and 98.6% for MTD and BD, respectively (p = 0.331). Renal pelvic injury was 8.1% for MTD and 10% for BD (p = 0.692). Stone clearance rates were 100% and 82.48% for MTD and BD, respectively (p = 0.098). LOS of both groups was not significantly different by multivariate analysis.

Conclusion: Both dilatation methods demonstrated comparable success rates, blood loss, and hospital stays in PCNL for renal stones. In the Thai population with a high prevalence of large renal stones, BD remains an effective option in most situations.

Keywords: Balloon dilator, Alken metal dilators, Percutaneous nephrolithotomy

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Introduction

Since 1976, PCNL has been established as the contemporary standard treatment for kidney stones larger than 2 cm in various types of patients, with multiple adaptations from the original methods to improve stone-free rates and reduce morbidities.[1-4] While some steps in PCNL may be omitted in specific conditions, tract dilation remains a crucial initial step to create a tract in the kidney parenchyma for the nephroscope and various types of stone breakers.

There are various techniques in tract dilation techniques for PCNL available in Thailand: Amplatz fascial dilators (AD), metal telescopic dilators (MTD), and balloon dilators (BD). The better method for tract dilation during PCNL is also controversial in the Thai population. In previous studies, Balloon dilator is considered the most effective and safe.[5] Due to the single-step technique, it decreased the tract dilation fluoroscopy time.[6] The mechanism of tract creation is by radial force against renal parenchyma after needle assessment and insertion of a guidewire. MTD utilizes both axial and radial force in multi-steps for tract dilation but is durable. Amplatz dilation is also multi-step in dilation but also practical and safe in patients who have previously had and did not have renal stone surgery.

In Thailand, the high prevalence and morbidity of kidney stones have prompted considerations on the choice of dilators.[7-8] Balloon and metal telescoping dilation are standard techniques developed over 30 years ago, but balloon dilation is still not widely popular in Asia.[9] Previous research indicates that BD may be associated with lower blood loss in patients without prior open renal surgery but demonstrates a lower success rate of dilation compared to MTDs in a limited study.[10-11]

This study aimed to compare the results of the use of BD and MTDs, as both devices have been extensively studied with mixed advantages and disadvantages. However, there is no definitive conclusion, and no studies have been conducted on kidney stone patients who underwent PCNL in the lower northern region of Thailand.

Patients and Methods

A total of 194 eligible patients who underwent PCNL at Naresuan University Hospital between January 2011 and July 2022 were included in this study. Without randomization, MTD was used for PCNL in the beginning period from January 2011 to December 2019, and then we used BD from January 2020 to July 2022 by two surgeons in our institute. The inclusion criteria comprised patients aged 15-80 who had undergone PCNL for kidney stones at the hospital during the specified period. Patients with a high risk of bleeding (e.g., cirrhosis, need for hemodialysis, or taking antiplatelet/anticoagulant drugs) were excluded, along with immunocompromised patients or those with active kidney infections that could lead to prolonged hospital stays. Patients with insufficient data due to medical record loss or loss of follow-up were also excluded. Out of the initial pool of samples, 144 patients were recruited and divided into two groups based on their tract dilation method. Group A (74 cases) underwent PCNL with MTD, while Group B (70 cases) received BD (as shown in Figure 1).

Clinical information assessment included age, sex, body mass index, presentation symptoms, previous kidney surgery history, and co-morbidities such as diabetes, chronic kidney disease, and hypertension. Laboratory data, including complete blood count, creatinine, estimated GFR rate, and urine culture, were also collected for all patients. A plain KUB film and CT KUB were done on all patients.

PCNL was performed step-by-step, starting with inserting a ureteric catheter into the renal pelvis and then placing the patient in a prone position. Renal stones were accessed with an 18 G needle under fluoroscopy guidance, and tract dilation was performed over a 0.035-inch stiff guidewire.

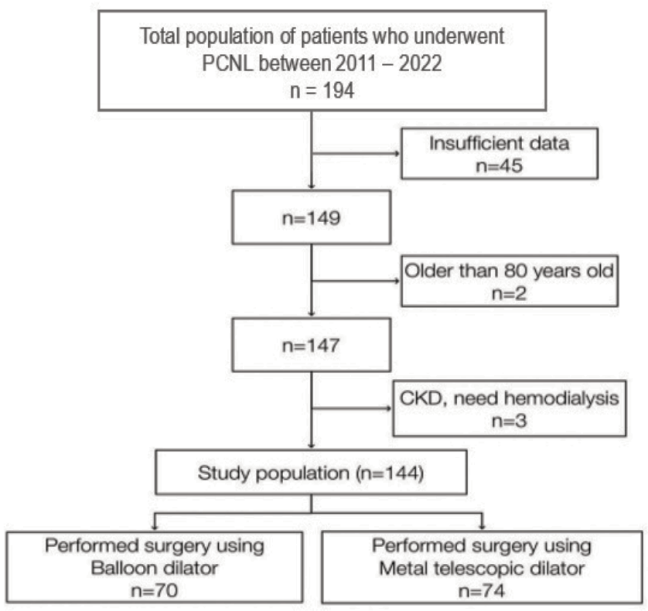

Figure 1 Population assignment description

Both brand new and re-sterilized balloon dilators (NephromaxTM, 30 Fr 12 cm) were used in the BD group, with inflation up to 10-12 ATM. Re-sterilized balloon dilators were used in 90% of patients. In the MTD group, dilation was performed from 9 to 30 Fr, followed by inserting a 30 Fr. working sheath. Stones were eliminated using pneumatic and ultrasonic lithotripters. A rigid nephroscope survey and fluoroscopic confirmation were conducted to assess stone clearance, and a nephrostomy tube was temporarily clamped in all cases.

The success rate of dilation, operative time, incidence of renal pelvis injury, postoperative ureteric stent need, blood transfusion, incidence of postoperative febrile UTI, postoperative hospital stays, and estimated blood loss were compared between the two groups. Stone clearance was calculated based on the average postoperative decrease in the maximum diameter of the renal stone from the KUB film at 1 month after PCNL. Failure of dilation is defined as the failure to insert an amplatz working sheath into the renal parenchyma or renal calyx.

Statistical analysis

Data were analyzed using Stata (version 18.0). Mean and standard deviation represented continuous variables, while frequency or percentage was used for categorical variables. Continuous variables were compared using an independent t-test, and a generalized linear model was employed to assess the mean difference and risk difference in the multivariable analysis.

Results

This study enrolled a total of 144 cases, with 74 cases in the MTD group and 70 cases in the BD group. Demographic data are presented in Table 1. Considering the gender observed between the two cohorts, the BD group showed a higher proportion of male patients than the MTD group. However, the gender distribution within the MTD group was contradictory. However, the p-value between the groups was 0.063, which is an insignificant difference. There are two significant differences in demographic data: chronic kidney disease and pre-operative imaging (CT /other imaging).

Table 1 Demographic data

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Mean age (years)	56.14	56.68	0.401
Sex (%)			0.063
Male	34 (45.9)	43 (61.4)	
Female	40 (54.1)	27 (38.6)	
BMI (kg/m²) (%)			0.67
< 30	55 (95.9)	61 (88.4)	
≥ 30	9 (14.1)	8 (11.6)	
Diabetic Mellitus (%)	20 (27.0)	15 (21.7)	0.426
Gout (%)	7 (9.5)	7 (10.0)	0.913
Chronic kidney disease (%)	6 (8.1)	16 (22.9)	0.014
Hypertension (%)	40 (54.1)	33 (47.1)	0.407
Imaging pre-op (CT/other) (%)	21 (28.4)	53 (75.7)	< 0.001
Flank pain (%)	34 (45.9)	23 (32.9)	0.108
Hematuria (%)	16 (21.6)	12 (17.1)	0.497

Clinical data of the population are shown in Table 2. The average stone size was 2.89 cm in the MTD group and 2.95 cm in the BD group. No significant differences between the two groups were observed in skin-to-stone distance, preoperative Hb, HCT, and BUN. However, the BD group had a higher proportion of complex stones, such as staghorn calculi and multiple stones, as well as higher levels of creatinine (1.11 mg/dL vs. 0.99 mg/dL, $p = 0.013$) and lower pre-operative eGFR compared to the MTD group (70.38 ml/min/1.73 m^2 vs. 81.51 ml/min/1.73 m^2, $p = 0.003$).

Table 2 Clinical data of the population

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Stone size (cm.)	2.895 (1.82 - 4.03)	2.95 (2.1 - 4.31)	0.37
Skin-to-stone distance (cm.)	7.36 ± 2.035	6.90 ± 1.952	0.388
No. of stone (%)			0.035
1	41 (56.2)	27 (38.6)	
> 1	32 (43.8)	43 (61.4)	
Staghorn calculi (%)	28 (37.8)	39 (55.7)	0.032
Previous kidney surgery (%)	21 (28.4)	10 (14.3)	0.04
Hb pre-op (g/dL) mean ± SD	13.11 ± 1.68	13.31 ± 2.03	0.520
HCT pre-op (%) mean ± SD	39.245 ± 4.6	40.235 ± 5.8	0.261
BUN pre-op (mg/dL) median	13.5 (11.9 - 16.5)	14.4 (10.8 - 17.68)	0.816
Creatinine pre-op (mg/dL)	0.99 ± 0.285	1.11 (0.89 - 1.4)	0.013
eGFR pre-op (ml/min/1.73 m^2)	81.51 ± 21.43	70.38 ± 22.84	0.003

The incidence of renal pelvis injury and the need for a stent placement are not significantly different between the MTD and BD groups based on the data from Table 3. However, the MTD group had a slightly shorter operative time than the BD group; the BD group experienced less estimated blood loss during surgery. However, this study found no statistically significant differences in the incidence of renal pelvis injury, the need for a DJ stent during surgery, the amount of blood loss during surgery, and the time required between the two patient groups.

Table 3 Intraoperative data

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Renal pelvis injury (%)	6 (8.1)	7 (10)	0.692
Estimated blood loss (ml)	181.00 (50 - 300)	173.79 (30 - 262.50)	0.624
Stent needed (%)	19 (25.7)	18 (25.7)	0.996
Operative time (min)	50 (35 - 85)	55 (34 - 85)	0.834

Even though more patients in the MTD group had previous kidney surgery than in the BD group (28.4% vs. 14.3% respectively, $p = 0.04$), in postoperative data analysis, the success rates of dilation of the two groups were comparable, and the stone clearance rates did not differ significantly (Table 4). The postoperative fever rate, blood transfusion rate, and laboratory data, including Hb, Hct, and positive urine culture, did not show statistically significant variations. However, postoperative hospital stay was significantly shorter in the BD group compared to the MTD group (4.19 ± 2.14 days and 5.01 ± 2.36 days, respectively; $p = 0.029$) (Table 4).

Table 4 Postoperative outcomes

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Success of dilation (%)	71 (95.5)	69 (98.6)	0.331
Stone clearance rate: mean ± SD	83.149 ± 2.57	74.432 ± 28.96	0.045
Postoperative febrile UTI (%)	9 (12.2)	15 (22.1)	0.116
Blood transfusion (%)	7 (9.5)	9 (12.9)	0.517
Post-op. hospital stays (days): mean ± SD	5.01 ± 2.36	4.19 ± 2.14	0.029
12 hr. Hb post-op (g/dL): mean ± SD	11.55 ± 2.03	11.83 ± 1.91	0.384
12 hr. HCT post-op (%): mean ± SD	35.03 ± 4.75	35.88 ± 5.37	0.328
Urine culture positive (%)	3 (33.3)	6 (66.7)	0.263
Mean different Hb (%)	1.88 ± 2.65	1.96 ± 3.52	0.439

In assessing stone clearance, we classified it into two categories: "stone-free," representing cases with 100% clearance, and "residual stone," representing any remaining stone after the procedure. The BD group had 41.4% of patients classified as stone-free, while the MTD group had 51.4% of stone-free cases, but there was no statistically significant difference between the two groups (p-value = 0.247) (Table 5).

Table 5 Stone clearance rate determined by the number of patients with residual stones or classified as stone-free, compared to the MTD and BD groups

	MTD Group A (n = 74)	BD Group (n = 70)	Total	*P*-value
Stone-free (%)	38 (51.4)	29 (41.4)	67	0.247
Residual stone (%)	36 (48.6)	41 (58.6)	77	0.247
Total	**74**	**70**	**144**	

Figure 2 illustrates the number of patients and length of hospital stay in both groups. The Crude analysis of generalized linear model for mean difference revealed that the BD group had a significantly shorter hospital stay by 0.827 days than the MTD group (p-value = 0.028). However, after accounting for other factors affecting the duration of hospital stay, such as the period of surgery, history of previous kidney surgery, and chronic kidney disease, the multivariable analysis showed that the post-operative hospital stays for patients using BD was only 0.374 days less than the MTD group. This difference is statistically insignificant (adjusted mean difference = -0.374, p = 0.512) (Table 6 and Figure 2).

Figure 3 illustrates the number of patients and their stone clearance outcomes. Additional analysis of the stone clearance rate, using a generalized linear model for risk difference with the result of stone clearance (yes or no revealed a 9.9% lower chance of stone clearance in the BD group compared to the MTD group. However, when other factors that may affect the stone clearance rate, such as stone size, history of previous kidney surgery, type of kidney stone, and number of stones, were considered, multivariable analysis showed that the BD group had a 3.9% lesser chance of stone clearance than those who used the MTD method (95% CI - 0.20 to 0.12, p = 0.627) (Table 6).

Table 6 Results of the multivariable analysis of postoperative hospital stay and stone clearance rate

Outcomes	Crude difference (BD – MTD)	95% (CI)	*P*-value	Effect size (adjusted difference)	95% (CI)	*P*-value
Post-operative hospital stays (Mean difference)	-0.827	- 1.564 - 0.091	0.028	- 0.374	- 1.490 - 0.745	0.512
Stone clearance rate (Risk difference)	-0.099	- 0.262 - 0.064	0.234	- 0.039	- 0.200 - 0.120	0.627

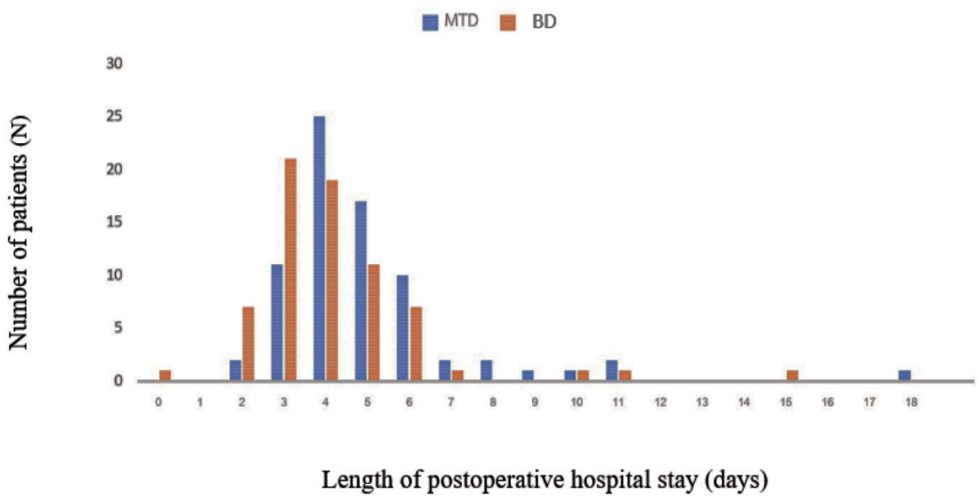

Figure 2 Number of patients and length of hospital stay in both groups

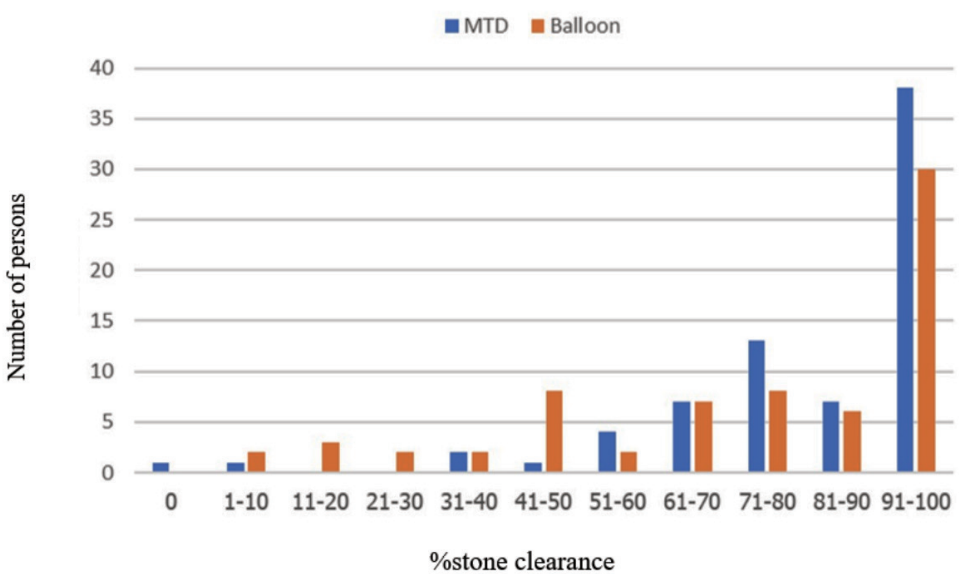

Figure 3 Number of patients and stone clearance rate in both groups

Discussion

The data from the two study groups showed remarkable similarity, with the difference being pre-operative imaging and underlying chronic kidney disease. Recently, non-contrast CT KUB was used as a standard study before PCNL. Therefore, the BD group had a higher rate of CT than the MTD group. However, we found that this factor had no significant association with the operative outcome in PCNL.

In the BD group, patients had slightly higher stone burden and lower estimated GFR in their clinical profiles. However, there were no differences in intraoperative results such as operative time, blood loss, and renal pelvic injury. The significant outcomes in this study were related to post-operative results in univariable analysis, specifically stone clearance and length of hospital stay. Still, the multivariable analysis showed no significant differences between the two groups.

BD involves a single-step dilation with radial force acting on kidney parenchyma, while MTD utilizes axial and radial force in multi-step for tract dilation. Both techniques aim to expand the parenchymal tract in the kidney and soft tissue up to 30 Fr. in standard PCNL. Different mechanisms of dilation may affect the result of PCNL.

Previously, MTD had the advantage of being durable and reusable, with a higher success rate in patients who had undergone previous kidney surgery.[12] However, it also carried the risk of forward perforation, necessitating the surgeon's awareness and frequent fluoroscopic checks during MTD dilation.

Eventually, there is no difference in the success rate of dilation in our study. However, according to the significant patients who had previous kidney surgery and increasing popularity of BD, we recommend preparing MTD spare for patients with prior surgery.

The use of balloon dilators was claimed to expedite the dilation process, but no significant difference in operative time was observed between the 2 groups. It appears that the disparity in stone burden between the groups had a more substantial impact on the total procedure time than the type of dilator used.

A previous study by Lopes et al. showed conflicting results regarding the efficacy of balloon and MTD methods in managing intraoperative blood loss. Kukreja et al. proposed various factors that affect significant blood loss during PCNL. Their review suggested that using Amplatz and balloon dilators demonstrated an observed correlation with reduced blood loss.[13] In contrast, our findings indicate a lack of apparent difference in hemoglobin change between the two groups.

In this study, balloon dilators were disinfected using Ethylene Oxide sterilization. Approximately 90% of patients in the balloon group received re-sterilized BD. Unfortunately, non-inflated reused BDs often had larger diameters than the new ones. Additionally, we had to dilate the tract with fascial dilators up to 14 Fr before inflating the balloon for insertion. However, there is no subgroup comparison between re-used and brand-new balloon dilators.

Non-randomized dividing of the population could be our limitation and might have some bias in patient selection.

Conclusion

Based on our experience, both metal and balloon dilators can safely be used for PCNL in treating large renal stones without compromising procedural efficacy. There is no significant difference in success rate and complications in both groups. Further studies with a larger population may be conducted to improve liability and decrease selective bias.

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