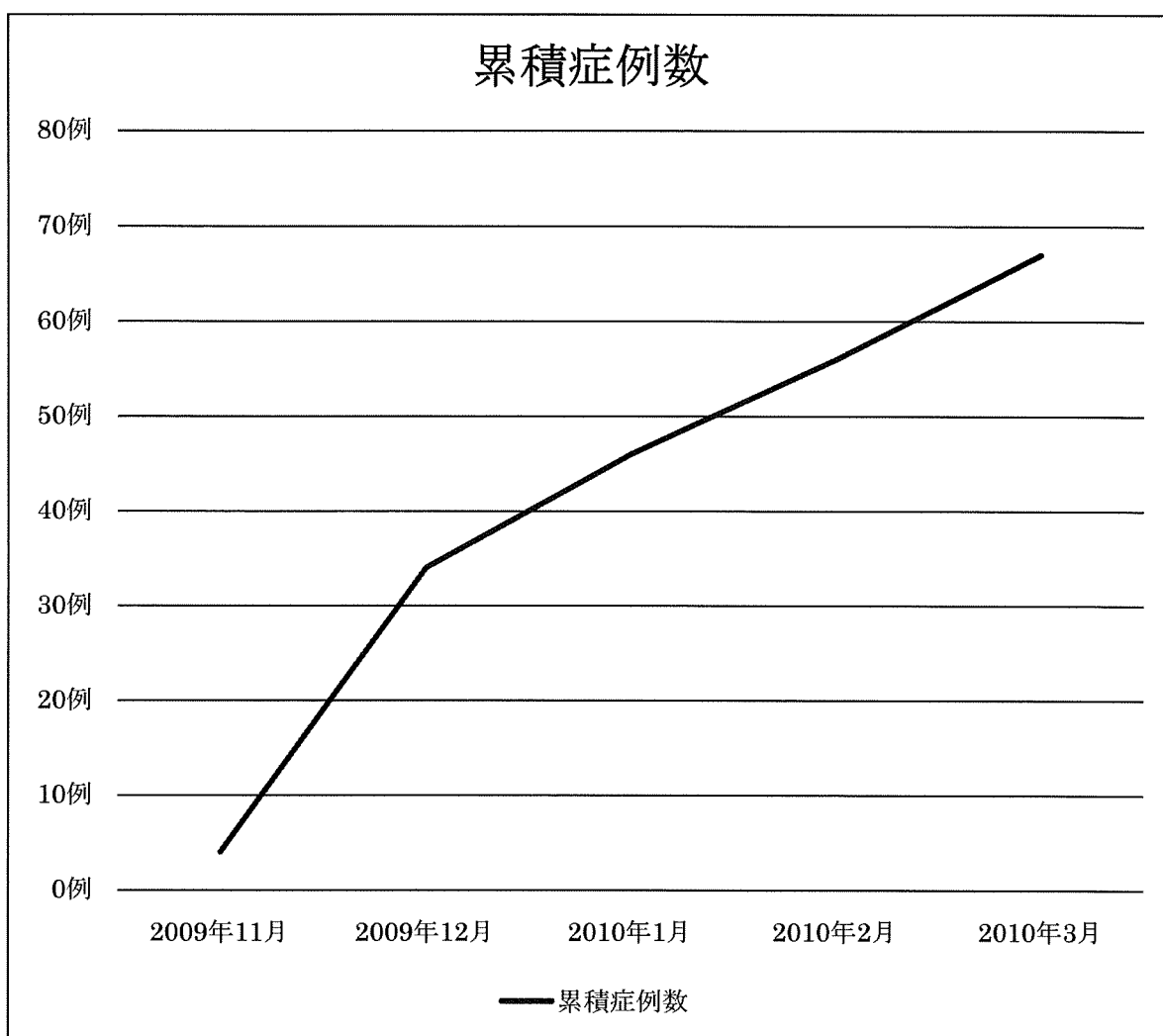


CLASS Tokyo study 症例登録

2010年3月31日現在 現況報告

全症例数

	2009年11月	2009年12月	2010年1月	2010年2月	2010年3月	計
症例数	4例	30例	12例	10例	11例	67例
累積症例数	4例	34例	46例	56例	67例	67例

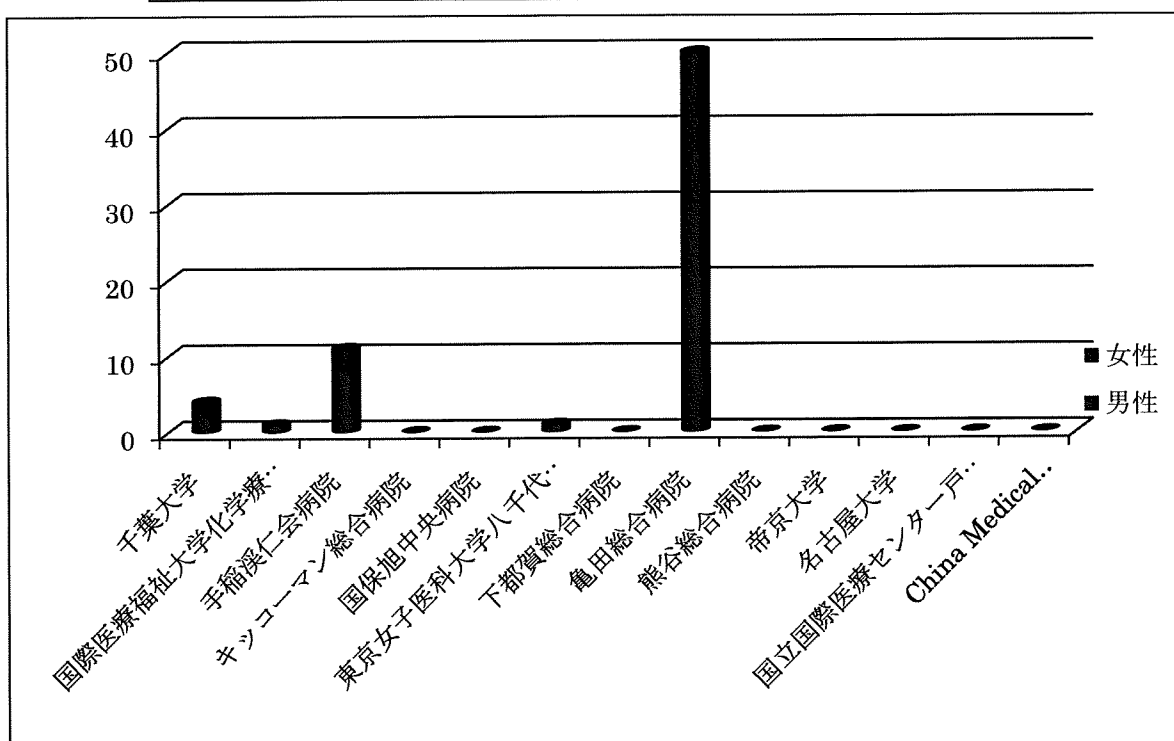


CLASS Tokyo study 症例登録

2010年3月31日現在 現況報告

施設毎の登録状況

施設	患者の性別		施設小計
	男性	女性	
千葉大学	2	2	4
国際医療福祉大学化学療法研究所附属病院	1	0	1
手稲溪仁会病院	8	3	11
キッコーマン総合病院	0	0	0
国保旭中央病院	0	0	0
東京女子医科大学八千代医療センター	1	0	1
下都賀総合病院	0	0	0
亀田総合病院	30	20	50
熊谷総合病院	0	0	0
帝京大学	0	0	0
名古屋大学	0	0	0
国立国際医療センター戸山病院	0	0	0
China Medical University Hospital	0	0	0
合計	42	25	67



パネルディスカッション 1

「急性胆管炎，胆嚢炎診療ガイドライン，Tokyo Guideline の検証」

平成 21 年 9 月 19 日（土） 第 1 会場 8：30～10：30

司会 吉田 雅博 国際医療福祉大学臨床医学研究センター
 真弓 俊彦 名古屋大学医学部救急部・集中治療部
 総括発言 高田 忠敬 帝京大学医学部外科

- P1-1 国内版胆道炎ガイドラインと国際版 Tokyo Guidelines における診断基準の診断精度の検証
 名古屋第二赤十字病院総合内科 横江 正道, 他
- P1-2 被引用状況からみた Tokyo Guidelines の国際的な評価と影響
 帝京大学医学部外科 三浦 文彦, 他
- P1-3 Cholangitis-Reevaluation of Tokyo Guideline
 A Retrospective Analysis of Limited Period Data for International Study
 Surgical Gastroenterology Division, Dept of General Surgery, Postgraduate Institute of Medical Education
 and Research, Chandigarh, India Rajesh Gupta, 他
- P1-4 国際版ガイドラインの検証を目的とした調査について
 東邦大学医学部外科学第三講座 吉田 祐一, 他
- P1-5 急性胆管炎の診断基準・重症度判定についての前向き観察研究について
 千葉大学大学院医学研究院腫瘍内科学 露口 利夫, 他

シンポジウム

シンポジウム 1

第1日目 3月18日(木) 9:02~11:30 第1会場

ガイドラインの検証と普及(1)急性胆道炎(2)急性膵炎

司会	名古屋大学救急・集中治療医学 化学療法研究所附属病院	真弓 俊彦 吉田 雅博
特別発言	日本腹部救急医学会名誉理事長 帝京大学名誉教授	高田 忠敬

- SS1-01 実地医科からみた「急性胆管炎、胆嚢炎の診療ガイドライン」の検証
—診断、重症度判定を中心に—
大垣市民病院消化器科 桐山 勢生
- SS1-02 胆道炎ガイドラインの診断基準は Charcot3 徴・Murphy 徴候
を超えられるか?
名古屋第二赤十字病院総合内科 横江 正道
- SS1-03 急性胆管炎の診断基準・重症度判定についての前向き観察研究
千葉大学腫瘍内科学 露口 利夫
- SS1-04 Tokyo Guidelines の国際的な評価と影響についての文献的考察
帝京大学外科 三浦 文彦
- SS1-05 急性閉塞性化膿性胆管炎(AOSC)に対する内視鏡治療成績の検討
<急性胆管炎診療ガイドライン重症度判定基準の問題点>
東京歯科大学市川総合病院消化器内科 貝田 将郷
- SS1-06 外科治療からみた高齢者急性胆道炎における問題点
八王子消化器病院外科 鈴木 修司
- SS1-07 急性膵炎ガイドライン：問題点と今後の展望
帝京大学外科 和田 慶太
- SS1-08 重症度判定基準(2008)による重症急性膵炎症例の再検討
札幌医科大学外科学第一 木村 康利
- SS1-09 急性膵炎重症度判定基準の改訂とガイドライン 2010
国立病院機構仙台医療センター外科 武田 和憲
- SS1-10 急性膵炎診療ガイドライン 2010 の検証—初期治療と感染合併症
東北大学消化器内科 廣田 衛久
- SS1-11 重症急性膵炎の治療変遷と成績からみた今後の展望
公立豊岡病院組合立豊岡病院但馬救命救急センター 小林 誠人

第 23 回ヨーロッパ外科感染症学会シンポジウム

2010 年 3 月 9 日～13 日 ドイツミュンヘン市において開催

**BILIARY TRACT INFLAMMATION: VALIDATION OF
THE TOKYO GUIDELINES FOR THE MANAGEMENT
OF ACUTE BILIARY TRACT INFLAMMATION**

司会 吉田雅博 研究代表者
真弓俊彦 研究分担者



**BILIARY TRACT INFLAMMATION: VALIDATION OF THE TOKYO GUIDELINES FOR THE
MANAGEMENT OF ACUTE BILIARY TRACT INFLAMMATION**

**Thursday, March 11th, 2010
p.m.**

Moderators: Toshihiko Mayumi, Nagoya, Japan
Masahiro Yoshida, Tokyo, Japan

**Why are International Guidelines for the Management of Acute Cholangitis and Acute
Cholecystitis Required to be Validated?**

M. Yoshida, Tokyo, Japan

**Difference between Tokyo Guidelines and Japanese Guidelines for the Management of Acute
Cholangitis and Acute Cholecystitis**

T. Mayumi, Nagoya, Japan

The Clinical Evaluation of the Tokyo Guidelines 2007 Based on Actual Clinical Cases

M. Yokoe, Nagoya, Japan

**Follow-Up of International Guidelines for the Management of Acute Cholangitis and Acute
Cholecystitis: A European Perspective**

D. J. Gouma, Amsterdam, Netherlands

Applicability of Tokyo Guidelines in Different Settings with Regard to Etiology and Presentation

R. Gupta, Chandigarh, India

**A Prospective Study to Validate the International Guidelines for the Management of Acute
Cholangitis and Acute Cholecystitis**

T. Tsuyuguchi, Chiba, Japan

Under the auspices of the Japan Society for Surgical Infection (JSSI)

MARCH
9TH - 13TH, 2010
MUNICH, GERMANY

**8TH WORLD CONGRESS ON
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TSIS 2010**

SELECTED PAPERS

Editor **Eugen Faist**

MONDUZZI EDITORE | PROCEEDINGS

Difference between Tokyo Guidelines and Japanese Guidelines of acute cholangitis and cholecystitis

Toshihiko Mayumi¹, Masamichi Yokoe², Masahiro Yoshida³, Tadahiro Takada⁴ and Yoshinobu Sumiyama⁵

¹ Department of Emergency and Critical Care Medicine, Nagoya University Graduate School of Medicine, Nagoya, Japan; ² General Internal Medicine, Japanese Red Cross Society Nagoya Daini Hospital, Nagoya, Japan; ³ Department of Hemodialysis and Surgery, International University of Health and Welfare, Clinical Research Center, Kaken Hospital, Chiba, Japan; ⁴ Chairman of the Board of Directors, Japanese Society of Hepato-Biliary-Pancreatic Surgery, Department of Surgery, Teikyo University School of Medicine, Tokyo, Japan; ⁵ Chairman of the Board of Directors, Japan Society for Surgical Infection, Chairman of the Toho University, Tokyo, Japan

Summary

Japanese Guidelines (JGL) and International Guidelines (Tokyo Guidelines: TGL) for the management of acute cholangitis and cholecystitis were published in September 2005, and in January 2007, respectively. Diagnosis and severity criteria of acute cholangitis and cholecystitis are defined for the first time in the world by these two Guidelines. Since there are many differences between the two Guidelines, these should be validated using retrospective and prospective clinical data.

Introduction

Japanese Guidelines (JGL) for the management of acute cholangitis and cholecystitis were published in September 2005¹⁾, and International Guidelines (Tokyo Guidelines: TGL) for the management of the diseases were published in January 2007²⁻⁴⁾. Diagnosis and severity criteria of acute cholangitis and cholecystitis are defined for the first time in the world. But there are many differences between the two guidelines.

Materials and methods

Here, we elucidate the differences of the diagnosis and severity criteria of acute cholangitis and cholecystitis of these two Guidelines.

Results

Many differences exist between TGL and JGL. Diagnosis criteria of both acute cholangitis and cholecystitis of the two Guidelines are different (Table 1-4)¹⁻⁴. Moderate acute cholangitis and cholecystitis of TGL is defined as the disease that does

A. Clinical context and clinical manifestations	1	History of biliary disease
	2	Fever and/or chills
	3	Jaundice
	4	Abdominal pain (RUQ or upper abdominal)
B. Laboratory data	5	Evidence of inflammatory response ^a
	6	Abnormal liver function tests ^b
C. Imaging findings	7	Biliary dilatation, or evidence of an etiology (stricture, stone, stent, etc)
<u>Suspected diagnosis</u>	Two or more items in A	
<u>Definite diagnosis</u>	Charcot's triad (2+3+4)	
	Two or more items in A + both items in B and item C	

^a Abnormal WBC count, increased of serum CRP level, and other changes indicating inflammation, ^b Increased serum ALP, γ -GTP(GGT), AST, and ALT levels

Tab. 1 - Tokyo Guidelines (TGL) diagnostic criteria for Acute Cholangitis.

A	1	Fever
	2	Abdominal pain (RUQ pain and upper abdominal)
	3	Jaundice
B	4	Increased serum ALP, γ -GTP
	5	Increased WBC count, serum CRP level
	6	Imaging findings (Biliary dilatation, stricture and stone)
<u>Suspected diagnosis</u>	one item in A + two or more items in B	
<u>Definite diagnosis</u>	Charcot's triad (1+2+3)	
	one item in A + all items in B	

Tab. 2 - Japanese Guidelines (JGL) diagnostic criteria for Acute Cholangitis.

A. Local signs of inflammation etc.	1	Murphy's sign
	2	RUQ mass/pain/tenderness
B. Systemic signs of inflammation etc.	1	Fever
	2	Elevated CRP
	3	Elevated WBC count
C. Imaging findings	Imaging findings characteristic of acute cholecystitis	
Definite diagnosis	One item in A and one item in B are positive	
	C confirms the diagnosis when acute cholecystitis is suspected clinically	

Note: acute hepatitis, other acute abdominal disease, and chronic cholecystitis should be excluded

Tab. 3 - Tokyo Guidelines (TGL) diagnostic criteria for Acute Cholecystitis.

A.	RUQ pain and epigastralgia
	Tenderness
	Muscle Defense
	Murphy sign
B	Fever
	Increased WBC count or serum CRP level
C	Imaging findings ^a
Suspected diagnosis	<u>one item in A + one item in B</u>
Definite diagnosis	Suspected diagnosis (one item in A + one item in B) + C

^a US: sonographic Murphy's sign, thickened GB wall, enlarged GB, Incarcerated gallstone, Sonolucent layer in GB wall etc)

Tab. 4 - Japanese Guidelines (JGL) diagnostic criteria for Acute Cholecystitis.

not respond to the initial medical treatment, whereas, that of TGL is defined as abnormality of laboratory data and image findings. Therefore, treatment strategies of the diseases are also different, although both Guidelines recommend that therapies of the diseases depend on the severity of the diseases.

Conclusions

The diagnosis and severity criteria are defined based on expert's opinions. Therefore, we need verify these Guidelines using retrospective and prospective clinical data. To evaluate these Guidelines, CLASS Tokyo Study (prospective registry of acute cholangitis) has been began (<http://class.umin.jp/english/index.html>).

References

1. The working group for publication of guidelines for the management of acute cholangitis and cholecystitis. Evidence-based practice guidelines for the management of acute cholangitis and cholecystitis. Igaku Tosho Shuppan Co.Ltd, Tokyo, 2005 (in Japanese).
2. Takada T, Kawarada Y, Nimura Y, et al. Background: Tokyo Guidelines for the management of acute cholangitis and cholecystitis. *J Hepatobiliary Pancreat Surg* 14:1-10, 2007.
3. Wada K, Takada T, Kawarada Y, et al. Diagnostic criteria and severity assessment of acute cholangitis: Tokyo Guidelines. *J Hepatobiliary Pancreat Surg* 14:52-8, 2007.
4. Hirota M, Takada T, Kawarada Y, et al. Diagnostic criteria and severity assessment of acute cholecystitis: Tokyo Guidelines. *J Hepatobiliary Pancreat Surg* 14:78-82, 2007.

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The Clinical Evaluation of the Tokyo Guidelines 2007 Based on Clinical Cases

Masamichi Yokoe¹, Toshihiko Mayumi², Masahiro Yoshida³, Tadahiro Takada⁴ and Yoshinobu Sumiyama⁵

¹ General Internal Medicine, Japanese Red Cross Society Nagoya Daini Hospital, Nagoya, Japan; ² Department of Emergency and Critical Care Medicine, Nagoya University Graduate School of Medicine, Nagoya, Japan; ³ Department of Hemodialysis and Surgery, International University of Health and Welfare, Clinical Research Center, Kaken Hospital, Chiba, Japan; ⁴ Chairman of the Board of Directors, Japanese Society of Hepato-Biliary-Pancreatic Surgery, Department of Surgery, Teikyo University School of Medicine, Tokyo, Japan; ⁵ Chairman of the Board of Directors, Japan Society for Surgical Infection, Chairman of the Toho University, Tokyo, Japan

Summary

“Tokyo Guidelines (TGL)”, the world’s first guidelines for biliary tract inflammation, was published in 2007. We have to evaluate TGL in order to ensure the accuracy on actual cases. Using TGL and Japanese Domestic Guidelines (JGL), we reviewed 74 cases of cholangitis, and 81 cases of cholecystitis that were clinically diagnosed by physician as an initial diagnosis on admission. On this article, we especially focused on 4 cases that had different diagnosis between TGL and JGL. On acute cholangitis, the difference of both guidelines is value of Charcot’s triad. And on acute cholecystitis, the difference of both guidelines is based on the range of abdominal pain (ex. RUQ only or not)

Introduction

There were no evidenced-based-criteria for the diagnosis, severity assessment, of treatment of acute cholecystitis or acute cholangitis¹⁾, before publication of JGL and TGL. 2 years have passed after publication of TGL, we have to evaluate TGL to ensure the accuracy on actual cases. We retrospectively reviewed our biliary tract inflammation cases.

Materials and methods

74 Acute cholangitis cases and 81 Acute cholecystitis cases that were clinically

diagnosed as an initial diagnosis on admission during the period from Nov.2004 to Nov. 2005. We applied TGL & JGL diagnostic criterion.

Results

Acute cholangitis (M:F = 39:35, 69.2±15.2yo) TGL: Suspected diagnosis = 9cases(12.2%), Definite diagnosis = 43cases(58.1%). JGL: Suspected diagnosis = 30cases(40.5%), Definite diagnosis = 30cases(40.5%).

Case1:TGL = Definite, JGL = Suspected 74y.o. Male. Only epigastralgia(no RUQ pain) and 5 times vomit. He went to clinic and took CT scan and EGD, but origin wasn't clear. He was transferred. No fever. WBC13400, ALT64, ALP314, GGT92, T-Bil 2.02, CRP1.08, GB stone only.

Case2:TGL = not match, JGL = Definite 81y.o. Female. Vomited several times, and abdominal distention. She came to our ER. No abdominal pain and high fever. WBC13300, ALT250, ALP1468, GGT330, T-Bil5.98, CRP23.61, GB stones and CBD stones were pointed out.

Acute cholecystitis (M:F = 49:32, 69.0±15.0yo) TGL: Definite diagnosis = 66cases(81.5%). JGL: Suspected diagnosis = 14cases(17.3%), Definite diagnosis = 56cases(69.1%).

Case3, TGL = definite, JGL = Suspected 66y.o. Female. 10years ago, GB stone was pointed out. In July, after dinner, she had RUQ pain and came to ER. RUQ tenderness(+), no fever. WBC2100, AST594, ALT336, ALP813, GGT361, T-bil 1.80, CRP1.32, GB stone & CBD stones: not detected.

Case4: TGL = not match, JGL = Definite 67y.o. Male. He had fever and epigas-

TGL : Acute Cholangitis Diagnostic Criteria			case1	case2
A. Clinical context and clinical manifestations	1	History of biliary disease	No	No
	2	Fever and/or chills	No	No
	3	Jaundice	Yes	Yes
	4	Abdominal pain (RUQ or upper abdominal)	Yes	No
B. Laboratory data	5	Evidence of inflammatory response ^a	Yes	Yes
	6	Abnormal liver function tests ^b	Yes	Yes
C. Imaging findings	7	Biliary dilatation, or evidence of an etiology	No	Yes
Suspected diagnosis	Two or more items in A			
Definite diagnosis	Charcot's triad (2+3+4)			
	2 or more items in A + both items in B and item C		Yes	

Tab. 1 - TGL diagnostic criteria for Acute Cholangitis (Diagnosis of Case 1&2).

JGL: Acute Cholangitis Diagnostic Criteria			case1	case2
A	1	Fever	No	No
	2	Abdominal pain (RUQ pain and upper abdominal)	Yes	No
	3	Jaundice	Yes	Yes
B	4	Increased serum ALP, γ -GTP	Half	Yes
	5	Increased WBC count, serum CRP level	Yes	Yes
	6	Imaging findings (Biliary dilatation, stricture and stone)	No	Yes
<u>Suspected</u>		one item in A + two or more items in B	Yes	
<u>Definite</u>		Charcot's triad (1+2+3)		
<u>diagnosis</u>		one item in A + all items in B		Yes

Tab. 2 - JGL diagnostic criteria for Acute Cholangitis (Diagnosis of Case 1&2).

TGL : Acute Cholecystitis Diagnostic Criteria			Case3	Case4
A. Local signs of inflammation etc.	1	Murphy's sign	No	No
	2	RUQ mass/pain/tenderness	Yes	No
B. Systemic signs of inflammation etc.	1	Fever	No	Yes
	2	Elevated CRP	Yes	Yes
	3	Elevated WBC count	No	Yes
C. Imaging findings	Imaging findings characteristic of acute cholecystitis		No	Yes
<u>Definite diagnosis</u>	One item in A and one item in B are positive		Yes	
	C confirms the diagnosis when acute cholecystitis is suspected clinically			

Tab. 3 - TGLdiagnostic criteria for Acute Cholecystitis (Diagnosis of Case 3&4).

tralgia (not RUQ pain). WBC15600, ALP311, GGT620, T-Bil 6.23, CRP9.76, CT scan showed GB stone and GB wall thickness.

Conclusions

74 cholangitis and 81 cholecystitis cases were retrospectively reviewed. We introduced discrepancies of these diagnoses between the guidelines on actual clinical cases.

JGL: Acute Cholecystitis Diagnostic Criteria		case3	case4
A.	RUQ pain and epigastralgia, Tenderness, Muscle Defense, Murphy sign	Yes	Yes
B	Fever	No	Yes
	Increased WBC count or serum CRP level	Yes	Yes
C	Imaging findings ^a	No	Yes
<u>Suspected diagnosis</u>	<u>one item in A + one item in B</u>	Yes	
<u>Definite diagnosis</u>	Suspected diagnosis (one item in A + one item in B) + C		Yes

Tab. 4 - JGLdiagnostic criteria for Acute Cholecystitis (Diagnosis of Case 3&4).

References

- 1 Takada T, Kawarada Y, Nimura Y, et al. Background: Tokyo Guidelines for the management of acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Surg 14:1-10, 2007.



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検索件数:3 件

試験ID/登録日	試験簡略名	対象疾患名	実施責任組織	試験進捗状況	試験問い合わせ窓口	閲覧	履歴
UMIN000003519 2010/04/22	自己免疫性膵炎 遺伝子研究	IgG4関連疾患、 自己免疫性膵炎、もしくは疑いのある症例。対照疾患としてアルコール性膵炎、特発性膵炎、胆石膵炎、シェーグレン症候群、甲状腺機能異常、原発性硬化性胆管炎、間質性腎炎、間質性肺炎、後腹膜繊維症、炎症性偽腫瘍等 IgG4関連疾患と鑑別を要する症例	関西医科大学内科学第三講座	限定募集中/Enrolling by invitation	関西医科大学	閲覧	履歴
UMIN000002552 2009/09/28	急性胆管炎の 向き観察研究	急性胆管炎	帝京大学	限定募集中/Enrolling by invitation	千葉大学大学院	閲覧	履歴
UMIN000001705 2009/02/13	急性胆管炎に対する胆管ドレナージ後の抗生剤投与期間に関する探索的試験	急性胆管炎	東京大学医学部	試験終了/Completed	東京大学医学部	閲覧	履歴

検索件数:3 件

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試験進捗状況	限定募集中/Enrolling by invitation :(参加医療機関受診中の患者が、基準を満たす場合に被験者になれる)
UMIN試験ID	: UMIN000002552
試験名	: 急性胆管炎の診断基準・重症度判定についての前向き観察研究
登録日(=情報公開日)	: 2009/09/28
最終データ内容更新日時	: 2010/03/29 21:36:24

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基本情報 (Basic information)		
項目(Item)	日本語(Japanese)	英語(English)
試験名 (Official scientific title of the study)	急性胆管炎の診断基準・重症度判定についての前向き観察研究	Diagnostic criteria and severity assessment in acute cholangitis: A prospective observational study
試験簡略名 (Title of the study (Brief title))	急性胆管炎の前向き観察研究	Diagnostic criteria and severity assessment in acute cholangitis (CLASS Tokyo)
試験実施地域 (Region)	日本/Japan アジア(日本以外)/Asia(except Japan)	

対象疾患(Condition)		
項目(Item)	日本語(Japanese)	英語(English)
対象疾患名 (Condition)	急性胆管炎	Acute cholangitis
疾患区分1 (Classification by specialty)	消化器内科学(肝・胆・膵)/Hepato-biliary-pancreatic medicine 感染症内科学/Infectious disease 消化器外科(肝・胆・膵)/Hepato-biliary-pancreatic surgery	
疾患区分2 (Classification by malignancy)	悪性腫瘍以外/Others	
ゲノム情報の取扱い (Genomic information)	いいえ/NO	

目的(Objectives)		
項目(Item)	日本語(Japanese)	英語(English)
目的1 (Narrative)	急性胆管炎診断におけるTokyo Guidelineの妥当性の検証	Diagnostic criteria and severity assessment in acute cholangitis: A

objectives1)	prospective observational study
目的2 (Basic objectives2)	有効性/Efficacy
目的2 -その他詳細 (Basic objectives - Others)	
試験の性質1 (Trial characteristics_1)	探索的/Exploratory
試験の性質2 (Trial characteristics_2)	
試験のフェーズ (Developmental phase)	該当せず/Not applicable

評価 (Assessment)

項目(Item)	日本語(Japanese)	英語(English)
主要アウトカム評価 項目 (Primary outcomes)	診断基準の妥当性 重症度別治療期間 重症度別致命率、臓器不全発症率	Diagnostic assessment in acute cholangitis Severity assessment in acute cholangitis Rate of mortality and organ failures in acute cholangitis
副次アウトカム評価 項目 (Key secondary outcomes)	他の重症度判定項目 胆管炎の原因疾患 胆道ドレナージ方法 使用抗生物質	Prognostic factors of acute cholangitis Etiologies of acute cholangitis Drainage methods of acute cholangitis Antibiotics

基本事項 (Base)

項目(Item)	日本語(Japanese)	英語(English)
試験の種類 (Study type)	観察/Observational	

試験デザイン (Study design)

項目(Item)	日本語(Japanese)	英語(English)
基本デザイン (Basic design)		
ランダム化 (Randomization)		
ランダム化の単位 (Randomization unit)		
ブラインド化 (Blinding)		
コントロール (Control)		
層別化 (Stratification)		