

## TG13 management bundles for acute cholangitis and cholecystitis

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Published online: 11 January 2013

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**Abstract** Bundles that define mandatory items or procedures to be performed in clinical practice have been increasingly used in guidelines in recent years. Observance of bundles enables improvement of the prognosis of target diseases as well as guideline preparation. There were no bundles adopted in the Tokyo Guidelines 2007, but the updated Tokyo Guidelines 2013 (TG13) have adopted this useful tool. Items or procedures strongly recommended in clinical practice have been prepared in the practical guidelines and presented as management bundles. TG13 defined the mandatory items for the management of acute cholangitis and acute cholecystitis. Critical parts of the bundles in TG13 include diagnostic process, severity

assessment, transfer of patients if necessary, therapeutic approach, and time course. Their observance should improve the prognosis of acute cholangitis and cholecystitis. When utilizing TG13 management bundles, further clinical research needs to be conducted to evaluate the effectiveness and outcomes of the bundles. It is also expected that the present report will lead to evidence construction and contribute to further updating of the Tokyo Guidelines.

Free full-text articles and a mobile application of TG13 are available via <http://www.jshbps.jp/en/guideline/tg13.html>.

**Keywords** Cholangitis bundle · Cholecystitis bundle

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## Introduction

A bundle is a group of therapies for a disease that, when implemented together, may result in better outcomes than if implemented individually. In recent years, bundles that define mandatory items or procedures to be performed in clinical practice have been increasingly used in guidelines [1]. Compliance with bundles results in the preparation of guidelines as well as an improved prognosis of targeted diseases arising from the use of the guidelines [2, 3]. Levy et al. [4] reported that data from 15,022 subjects at 165 sites were analyzed to determine compliance with bundle targets and association with hospital mortality, and compliance with the entire resuscitation bundle increased linearly from 10.9 % in the first site quarter to 31.3 % by the end of 2 years. Furthermore the odds ratio for mortality improved the longer a site was in the Surviving Sepsis Campaign, resulting in an adjusted absolute drop of 0.8 % per quarter and 5.4 % over 2 years.

Murata et al. [5, 6] examined a total of 60,842 patients with acute cholangitis using the Japanese national administrative database. This report demonstrated the improved prognosis of in-hospital mortality with odds ratio of 0.856 among patients who were managed with high compliance with the items of recommendation Grades A and B in Tokyo Guidelines 2007 (TG07) as compared with the patients who were low-compliance. This shows the importance of preparing bundles by setting the recommended items to be observed in the guidelines. Although TG07 did not prepare bundles at that time, the updated Tokyo Guidelines 2013 (TG13) have adopted the management bundles for acute cholangitis and cholecystitis. The care bundles are designed

to be easily achievable and sustainable both to implement and to audit.

Furthermore, we made a checklist. We hope to use the acute cholangitis and cholecystitis bundle checklist to help track your organization's compliance with implementing each element of these bundles.

## Efficacy of the bundle

In the process of developing TG13, mandatory items or procedures to be included in the management bundles have been discussed and defined among the Tokyo Guidelines Revision Committee members. The bundles have been developed and finalized by obtaining consensus. Based on the recommendations in TG13, items which are expected to yield favorable treatment results are included in the bundles. To underscore the time course or timing of the performance of each item, management bundles for acute cholangitis and cholecystitis have been developed. A checklist has also been prepared to confirm compliance with the bundles.

The bundles such as sepsis bundle [7–9], ventilator bundle [10, 11] or central line bundle [12], when implemented together, may result in better outcomes than if implemented individually. Good prognosis is also reported in cases in which a bundle has been achieved, but this may show that those cases which have achieved a bundle are in such good condition as to enable achievement of a bundle.

However, the improvement in prognosis in patients achieved through education concerning bundles demonstrates that implementation of bundles and education concerning them have been useful [9, 13].

## Controversial points and harmful effects of bundles

There are many problems to be solved for the spread and implementation of bundles. In the guidelines, even if useful items have been implemented, the prognosis in patients is not improved without common knowledge of management bundles among medical care workers [13]. Furthermore, it is not possible to put bundles into practice without sufficient manpower and equipment [14], which should be improved, if possible. If improvement is impossible, an alternative treatment should be provided or patients should be transferred to a medical facility where the contents of bundles can be put into practice [15].

There is also a concern that bundles are used not for the purpose of improving the prognosis in patients and increasing efficiency, but for limiting the contents of medical care to keep health care costs down. Furthermore,

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failure to carry out the contents of bundles should not lead to lawsuits [15].

### Acute cholangitis management bundle (Table 1)

Items in the cholangitis management bundle are described in Table 1. The content of every bundle is developed from the recommendation of TG13. The mandatory items or procedures to be included in the management bundles have

been discussed and defined among the Tokyo Guidelines Revision Committee members. The diagnostic criteria and the severity assessment of acute cholangitis in TG13 was made based on the article of Kiriya et al. [16].

### Acute cholecystitis management bundle (Table 2)

Items in the cholecystitis management bundle are described in Table 2. The content of every bundle is classified into

**Table 1** Management bundle of acute cholangitis

1. When acute cholangitis is suspected, diagnostic assessment is made using TG13 diagnostic criteria every 6–12 h
2. Abdominal X-ray (KUB) and abdominal US are carried out, followed by CT scan, MRI, MRCP and HIDA scan
3. Severity is repeatedly assessed using severity assessment criteria; at diagnosis, within 24 h after diagnosis, and during the time zone of 24–48 h
4. As soon as a diagnosis has been made, the initial treatment is provided. The treatment is as follows: sufficient fluids replacement, electrolyte compensation, and intravenous administration of analgesics and full dose of antimicrobial agents are provided
5. For patients with Grade I (mild), when no response to the initial treatment is observed within 24 h, biliary tract drainage is carried out immediately
6. For patients with Grade II (moderate), biliary tract drainage is immediately performed along with the initial treatment. If early drainage cannot be performed due to the lack of facilities or skilled personnel, transfer of the patient is considered
7. For patients with Grade III (severe), urgent biliary tract drainage is performed along with the initial treatment and general supportive care. If urgent drainage cannot be performed due to the lack of facilities or skilled personnel, transfer of the patient is considered
8. For patient with Grade III (severe), organ supports (noninvasive/invasive positive pressure ventilation, use of vasopressors and antimicrobial agents, etc.) are immediately performed
9. Blood culture and/or bile culture is performed for Grade II (moderate) and III (severe) patients
10. Treatment for etiology of acute cholangitis with endoscopic, percutaneous, or operative intervention is considered once acute illness has resolved. Cholecystectomy should be performed for cholelithiasis after acute cholangitis has resolved

*KUB* kidney–ureter–bladder, *US* ultrasonography, *CT* computed tomography, *MRI* magnetic resonance imaging, *MRCP* magnetic resonance cholangiopancreatography, *HIDA* hepatobiliary iminodiacetic acid

**Table 2** Management bundle of acute cholecystitis

1. When acute cholecystitis is suspected, diagnostic assessment is made using TG13 diagnostic criteria every 6–12 h
2. Abdominal US is carried out, followed by HIDA scan and CT scan if needed to make the diagnosis
3. Severity is repeatedly assessed using severity assessment criteria; at diagnosis, within 24 h after diagnosis, and during the time zone of 24–48 h
4. Take that cholecystectomy is performed into consideration, as soon as a diagnosis has been made, the initial treatment takes place involving the replacement of sufficient fluid after fasting, electrolyte compensation, intravenous injection of analgesics and full dose antimicrobial agents
5. For patients with Grade I (mild), cholecystectomy at an early stage within 72 h of onset of symptoms is recommended
6. If conservative treatment patients with Grade I (mild) is selected and no response to the initial treatment is observed within 24 h, reconsider early cholecystectomy if still within 72 h of onset of symptoms or biliary tract drainage
7. For patients with Grade II (moderate), perform immediate biliary drainage or drainage if no early improvement (or cholecystectomy in experienced centers) along with the initial treatment
8. For patients with Grade II (moderate) and III (severe) at high surgical risk, biliary drainage is immediately carried out
9. Blood culture and/or bile culture is performed for Grade II (moderate) and III (severe) patients
10. Among patients with Grade II (moderate), for those with serious local complications including biliary peritonitis, pericholecystic abscess, liver abscess or for those with gallbladder torsion, emphysematous cholecystitis, gangrenous cholecystitis, and purulent cholecystitis, emergency surgery is conducted (open or laparoscopic depending on experience) along with the general supportive care of the patient. If surgery cannot be performed due to the lack of facilities or skilled personnel, transfer of the patient is considered
11. For patients with Grade III (severe) with jaundice and those in poor general conditions, emergency gallbladder drainage is considered with initial therapy with antibiotics and general support measures. For patients who are found to have gallbladder stones during biliary drainage, cholecystectomy is performed at after 3 month interval after the patient's general conditions are improved

*US* ultrasonography, *CT* computed tomography, *HIDA* hepatobiliary iminodiacetic acid

**Table 3** Acute cholangitis bundle checklist

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- Repeat diagnosis every 6–12 h
  - Diagnostic imaging X-ray (KUB), US, CT scan, MRI, MRCP, HIDA scan
  - Severity assessment at diagnosis and within 24 h after a diagnosis
  - Repeat severity assessment every 24 h
  - Immediately start antibiotics administration and general supportive care
  - Grade I (mild): carry out biliary drainage when no symptom improvement is observed within 24 h
  - Grade II (moderate): carry out biliary drainage immediately
  - Grade III (severe): conduct emergency biliary drainage and perform organ support
  - Consider transfer when procedures are unavailable as above
  - Grade II (moderate) and III (severe): blood culture and bile culture
  - Consider surgical procedures to remove causes after biliary drainage and improvement of organ failure
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**Table 4** Acute cholecystitis bundle checklist

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- Repeat a diagnosis every 6–12 h
  - Diagnostic imaging US, HIDA scan and CT scan
  - Severity assessment at diagnosis and within 24 h after diagnosis
  - Repeat severity assessment every 24 h
  - Immediately initiate antibiotics administration and general supportive care
  - Grade I (mild): Cholecystectomy at an early stage within 72 h of onset of symptoms
  - Conservative treatment for Grade I (mild): Worsening condition or no improvement is in condition observed within 24 h. Reconsider early cholecystectomy if still within 72 h or biliary drainage (cholecystostomy)
  - Grade II (moderate): Immediate biliary drainage or drainage if no early improvement (or cholecystectomy in experienced centers) along with the initial treatment\*
  - After drainage treatment for Grade II (moderate): Elective cholecystectomy after symptom improvement at after 3 month interval
  - Poor local control\*\* for Grade II (moderate): Emergency abdominal drainage and/or cholecystectomy in experienced centers
  - Grade II (moderate) and III (severe) at high surgical risk: Immediately biliary drainage
  - Grade II (moderate) and III (severe): Blood culture and/or bile culture
  - Grade III (severe): Initiate therapy with antibiotics and general support measures. Conduct emergency biliary drainage as soon as stable
  - After drainage treatment for Grade III (severe): Elective cholecystectomy after symptom improvement at after 3 month interval
  - Consider transfer when procedures are unavailable as above
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\* see bundle No.4

\*\*see bundle No.10

the recommendation of TG13. The mandatory items or procedures to be included in the management bundles have been discussed and defined among the Tokyo Guidelines Revision Committee members. The diagnostic criteria and the severity assessment of acute cholecystitis in TG13 was made based on the article of Yokoe et al. [17].

### Check list for the use of management bundles for acute cholangitis and cholecystitis (Tables 3, 4)

A check list is shown for the effective use of bundles. The use of this list for medical care ensures standards, and is thought to improve effectiveness of the bundles. These check lists, including procedures, laboratories, monitoring and interventions required, should be placed by the bedside.

### Conclusions

Bundles consist of important items for the effective use of TG13. Compliance with the bundles is expected to improve the prognosis of acute cholangitis and acute cholecystitis. Reports from various facilities have demonstrated that improved prognosis is expected through the use of the Tokyo Guidelines for acute cholangitis and cholecystitis. Furthermore, good use of those reports will contribute to evidence construction and future revision of TG13.

**Acknowledgments** We would like to express our deep gratitude to the following organizations for their great support and guidance in the preparation of TG13: Japanese Society for Abdominal Emergency Medicine, Japan Biliary Association, Japan Society for Surgical Infection, and the Japanese Society of Hepato-Biliary-Pancreatic Surgery.

**Conflict of interest** None.

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