

Guideline for the  
**SURGICAL TREATMENT**  
of **GASTRIC CANCER**  
Recommendations Summary



Provincial Health Services Authority

## Disclaimer

*This guideline, for the surgical treatment of gastric cancer, was developed by the Surgical Standards Working Group (SSWG), and endorsed by the BC Cancer Gastrointestinal Tumour Group as of November 22, 2018. The recommendations in this guideline are not expected to be a replacement for independent professional judgment, nor are the recommendations considered the only approach to the surgical management of patients. All of the content is provided for information and education, and the authors, reviewers, and supporting institution(s) assume no responsibility or liability arising from any error or omission, or from the use of any information contained herein.*

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## Preamble

The development and implementation of an evidence-informed surgical guideline for gastric cancer is part of an overall strategy aimed to enhance the quality of surgical care, and ultimately to improve outcomes for gastric cancer patients. The Surgical Standards Working Group (SSWG) has reviewed and evaluated the clinical evidence, and developed key recommendations and associated quality indicators for their application to the management of surgical gastric cancer patients in British Columbia (B.C.). The BC Cancer Gastrointestinal (GI) Tumour Group provided the funding for this project. BC Cancer is a division of the Provincial Health Services Authority.

## Purpose

The purpose of this document is to outline evidence-informed recommendations for the surgical management of adult patients with stage I to IV gastric cancer. The recommendations are applicable to multidisciplinary teams, which include surgeons, medical oncologists, radiation oncologists, radiologists, pathologists, and gastroenterologists managing surgical gastric cancer patients in secondary and tertiary health care settings in B.C. Where appropriate, quality indicators are identified for the purposes of evaluation and/or standardization of practice.

## Development Approach

### Surgical Standards Working Group

Membership in the SSWG includes clinical representation from surgical oncology, general surgery, medical oncology, internal medicine, as well as a medical writer/researcher. Although patient perspectives and values were considered, patient and public input was not sought for the development of this guideline. Decisions on final recommendations were made by consensus, with a comprehensive review of the evidence followed by peer review.

### Literature Search Strategy and Evidence Review

This guideline was developed by systematically reviewing the available clinical literature. The *AGREE Reporting Checklist (2016)* was used to guide the content and reporting of information used for the development of this guideline.<sup>1</sup>

The detailed strategy was developed to address the following clinical questions: the optimal surgical setting, the optimal surgical treatment, and available standards on surgical techniques for gastric cancer surgery. When evidence was rated in systematic reviews or meta-analyses, the working group reported that rating according to the system used in the source document. When available in the sourced systematic reviews, the quality of evidence was reported according to the *Grading of Recommendations Assessment, Development, and Evaluation (GRADE)* system (see Table 1).<sup>2</sup>

The complete systematic search used to source the evidence, as well as the approach to evaluating and reporting on the quality of the evidence including the guideline adaptation approach, can be found in the original document, *Guideline for the Surgical Treatment of Gastric Cancer Version 1.0*. This document is available on the BC Cancer website.

TABLE 1 - GRADE CATEGORIES FOR EVALUATING THE BODY OF EVIDENCE<sup>2</sup>

Significance of the Four Levels of Evidence	
Quality Level	Definition
High****	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate***	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low**	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low*	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

*When available, the quality and associated confidence levels in the systematic reviews reported and referenced in this guideline were assigned by the authors of the systematic reviews according to the GRADE method.<sup>2</sup>*

### Developing Recommendations

The working group developed clinical recommendations, including evaluating the strength of recommendations. When the working group felt that the available evidence was insufficient or uncertain, or that the balance between desirable or undesirable effects was not as clear, the recommendation was rated as weak, and the working group provided a qualification for the recommendation and included the reason(s). When clinical evidence was insufficient, the working group chose to refrain from making a recommendation. Where appropriate and measurable, recommendations were adapted as quality indicators.

TABLE 2 - ASSESSING THE STRENGTH OF RECOMMENDATIONS

Strength of Recommendations - Descriptions	
Strong	When the working group felt that a recommendation was supported by sufficient clinical evidence, and that the balance between the desirable effects of an intervention versus the undesirable effects were sufficiently strong, the recommendation was rated by the working group as <b>strong</b> .
Weak	When the working group felt that the available evidence was insufficient or uncertain, or that the balance between desirable or undesirable effects was not as clear, the recommendation was rated as <b>weak</b> , and the working group provided a qualification for the recommendation and included the reason(s).

*\* The SSWG assigned the strength of individual recommendations after a review of the evidence, including assessment of the quality of evidence as rated in the included systematic reviews.*

## Peer Review Process

The purpose and intent of the peer review process was to gather feedback on the draft recommendations, to assess the applicability and feasibility of implementing the recommendations into practice, as well as to communicate and disseminate the best available evidence regarding surgical practice and/or settings for the delivery of gastric cancer surgery. The working group carefully considered the feedback provided from the peer review process, and recommendations were adjusted based on evaluation of the evidence, and working group consensus. More information about the peer review process and aggregate results are available from the BC Cancer GI Tumour Group.

## Recommendations

### Scope

The recommendations presented here are intended for surgeons and multidisciplinary teams managing adult gastric cancer surgical patients. These recommendations are intended to address questions around the optimal processes and settings for the surgical management of gastric cancer.

### Process Criteria

#### Care Delivery Criteria

#### Preoperative Workup/Staging for Gastric Cancer

##### *Recommendation 1*

- Preoperative computerized tomography (CT) of abdomen/pelvis/chest for staging is recommended, to assess local involvement and to exclude distant metastasis.<sup>3,4</sup> (*Strong Recommendation*)
- Positron emission tomography (PET) scan is not routinely indicated for gastric cancer staging.<sup>4</sup> (*Weak Recommendation*)
- With the exception of early gastric cancer or metastatic disease, diagnostic laparoscopy with peritoneal washings should ideally be performed before initiating treatment.<sup>4</sup> (*Strong Recommendation*)
- Endoscopic ultrasonography (EUS) may be considered for the preoperative locoregional staging of primary gastric cancer.<sup>5</sup> (*Weak Recommendation*)

##### *Qualifications and Key Evidence for Recommendation 1*

- Recommendations for CT and PET in staging of gastric cancer were endorsed from the results of the RAND/UCLA Expert Panel. CT of the abdomen (for evaluation local invasion and distant spread), and the pelvis (for intra-abdominal spread) were both deemed as *necessary*.<sup>4</sup> PET was not recommended for routine use in staging due to a lack of evidence on its utility in altering management in gastric cancer. Diagnostic laparoscopy was deemed *appropriate* to determine the presence of metastatic disease.<sup>4</sup>
- Based on *moderate*\*\*\* quality of evidence, EUS may be considered if the results are expected to change management.<sup>5</sup> EUS as a diagnostic tool is not considered optimal for either disease conformation or for exclusion particularly for distinguishing T1 tumours and determining lymph node status (positive versus negative).<sup>5</sup>

\* Indicates the quality of evidence reported according to the GRADE approach.<sup>2</sup>

## Surgical Margins

### *Recommendation 2*

- Surgery for gastric cancer should aim at achieving an R0 margin.<sup>3,6</sup> (*Strong Recommendation*)
- A multidisciplinary preoperative assessment of factors associated with positive margins (i.e. tumour size, T-stage, primary location, and differentiation), should be used to guide treatment decisions.<sup>6</sup> (*Weak Recommendation*)
- Intraoperative frozen sections analysis of margins should be performed in patients undergoing curative resection, to achieve a final negative margin with intraoperative re-excision.<sup>4,7</sup> (*Strong Recommendation*)
- Patients with negative results from intraoperative frozen sections, but a definite positive margin on final analysis should have a multidisciplinary review prior to consideration of surgical re-excision, in order to consider other factors that may affect patient survival.<sup>6,7</sup> (*Strong Recommendation*)
- Re-resection may be more beneficial in N0, N1, and early T-stage patients.<sup>6</sup> (*Weak Recommendation*)

### *Qualifications and Key Evidence for Recommendation 2*

- Recommendations on surgical margins were adapted in part from CCO's *Staging and Surgical Approaches in Gastric Cancer*, in addition to evidence from two systematic reviews.<sup>3,6,7</sup>
- The results from a systematic review of primary studies evaluating predictors of positive margins indicated that T-stage, tumour size, nodal involvement and histology were independently prognostic.<sup>6</sup> Primary tumour location was associated with positive resection margins on univariate analysis, with a higher ratio of total gastric involvement (i.e. linitus plastica) in patients with positive margins.<sup>6</sup>
- Evaluation of the evidence for the effect of positive margins on survival showed significant heterogeneity across studies; additionally margin status was found to lose its predictive ability in patients with advanced disease.<sup>6</sup>
- The recommendation for intraoperative frozen sections analysis of margins was in alignment with the RAND/UCLA Expert Panel, which considered this approach as *appropriate*.<sup>4</sup>

## Extent of Lymphadenectomy

### Recommendation 3

- A D2 lymphadenectomy is preferred for patients with curative-intent advanced gastric cancer based on observed DSS.<sup>8</sup> (*Weak Recommendation*)
- Due to increased post-operative mortality with D2 lymphadenectomy compared to D1, a D2 dissection should be performed **without** routine distal pancreatectomy and splenectomy.<sup>8</sup> (*Strong Recommendation*)
- In patients with T1N0 cancers or significant comorbidities, a D1 dissection may be performed.<sup>3</sup> (*Strong Recommendation*)

### Qualifications and Key Evidence for Recommendation 3

- D1 and D2 lymph node dissections are defined by resection of specific nodal stations, as per the most updated Japanese Gastric Cancer Treatment Guidelines.<sup>9</sup>
- A systematic review and meta-analysis of 5 randomized controlled trials (2515 patients) showed no significant difference in OS (quality of evidence *low*\*\*), and DFS (*moderate*\*\*\*), between D2 and D1 lymphadenectomy.<sup>8</sup> A D2 lymphadenectomy was associated with a significantly better DSS compared to D1 (HR 0.81, 95% CI 0.71 to 0.92) (*moderate*\*\*\*); however, D2 was associated with a higher post-operative mortality rate (RR 2.02, 95% CI 1.34 to 3.04) (*high*\*\*\*).<sup>8</sup> Evaluating the benefits and harms of extended lymphadenectomy (D2 compared to D1), Mocellin et al. calculated a net benefit of 33 deaths avoided for every 1000 patients treated with D2 lymphadenectomy (77/1000 avoided versus 38/1000 caused).<sup>8</sup>
- Based on a review of benefits and harms, the SSWG felt that patients would value the benefits from improved DSS. The SSWG recommended a D2 lymphadenectomy **without** routine distal pancreatectomy and splenectomy, with the exception for patients with T1N0 cancers or significant comorbidities, where a D1 lymphadenectomy is recommended.
- This recommendation is in alignment with CCO's *Staging and Surgical Approaches in Gastric Cancer*, as well as the RAND/UCLA Expert Panel.<sup>3,4</sup> Additionally, the RAND/UCLA qualified the approach as *appropriate*, but the necessity as indeterminate due to the wide variability in clinical circumstances.<sup>4</sup>

\* Indicates quality of evidence reported according to the GRADE approach.<sup>2</sup>



## Lymph Node Dissection/Evaluation

### Recommendation 4

- At least 16 lymph nodes should be assessed for adequate staging of curative-resected gastric cancer.<sup>10,11</sup> (*Strong Recommendation*)

### Qualifications and Key Evidence for Recommendation 4

- A systematic review of lymph node assessment in gastric cancer evaluated 25 retrospective studies including 74,228 patients, to determine the relationship between the extent of lymph node harvest on recurrence and long-term outcomes.<sup>10</sup> Two of three included studies showed a significantly longer DFS with more lymph nodes assessed.<sup>10</sup> OS was reported in 18 studies, with just over half showing improved OS with an increased number of lymph nodes assessed.<sup>10</sup> Four studies reporting OS for lymph node harvest by T-stage and eleven by N-stage showed inconsistent results.<sup>10</sup> The quality of evidence across outcomes was limited due to heterogeneity in surgical techniques, and confounding due to the effects of stage migration.<sup>10</sup>
- The SSWG agreed that assessing a larger number of lymph nodes allows for accurately staging patients, and is an appropriate target for surgical and pathological assessment. This is in alignment with both the CCO's *Staging and Surgical Approaches in Gastric Cancer*, as well as the RAND/UCLA Expert Panel who similarly found 16 lymph nodes to be both *appropriate* and *necessary*.<sup>3,4</sup>

## Open versus Laparoscopic Resection

### Recommendation 5

- If a laparoscopic resection is to be performed and is deemed oncologically appropriate, then it should be performed by surgeons who are experienced in both advanced laparoscopic surgery and gastric cancer management.<sup>4</sup> (*Weak Recommendation*)

### Qualifications and Key Evidence for Recommendation 5

- A systematic review including 11 trials and 2,335 randomized patients found there was no difference in short-term (30-day) mortality between laparoscopic and open gastrectomy (RR 1.6, 95% CI 0.50 to 5.10), based on *low\*\** quality evidence.<sup>12</sup> The results of three studies of 195 patients reported no significant difference in long-term mortality (HR 0.94, CI 0.70 – 1.25), based on *very low\** quality of evidence.<sup>12</sup>
- Although no statistically significant differences were identified in short- or long-term mortality between laparoscopic and open gastrectomy, the results across studies were inconsistent with large confidence intervals, and therefore significant benefits and harms of laparoscopic gastrectomy cannot yet be ruled out.<sup>12</sup>
- Studies evaluating the number of laparoscopic surgeries required to achieve proficiency were limited by heterogeneity in design, and were not adequately designed to address survival.
- The SSWG found it appropriate to endorse the RAND/UCLA approach, which assessed the technique as *appropriate* but recommended oncologic and laparoscopic expertise.<sup>4</sup>

\* Indicates quality of evidence reported according to the GRADE approach.<sup>2</sup>

## Surgical Considerations in Metastatic Disease

### *Recommendation 6*

- In patients with metastatic disease, surgery should only be considered for palliation of symptoms that cannot be addressed through less invasive means (i.e. radiation, chemotherapy, endoscopic stenting).<sup>3,13</sup> (*Strong Recommendation*)
- In patients with metastatic disease, nonsurgical management options are preferred in patients without significant symptoms.<sup>3,13</sup> (*Strong Recommendation*)

### *Qualifications and Key Evidence for Recommendation 6*

- A systematic review of the benefits and limitations of non-curative surgery in advanced gastric cancer evaluated morbidity, mortality and survival.<sup>13</sup> The primary intention to treat for relief of symptoms was identified in only 5 studies.<sup>13</sup> Median and one-year survival were poor with significant variability in surgical approaches across studies.<sup>13</sup>
- A systematic review of the effectiveness of palliative surgical interventions was limited by retrospective studies, a lack of a validated tool and indirectness when determining quality of life.<sup>14</sup>
- The REGATTA phase 3 RCT did not show a survival benefit for patients treated with gastrectomy plus chemotherapy versus chemotherapy alone; the study was closed after the first interim analysis.<sup>15</sup>
- In light of the above evidence, the SSWG adapted the above recommendation from the CCO approach given the high rates of surgical morbidity, and a lack of survival benefit for surgery in metastatic disease.<sup>3,13,15</sup>

## *Care Coordination Criteria*

### **Multidisciplinary Care**

### *Recommendation 7*

- Multidisciplinary decision-making is recommended after staging but before treatment initiation.<sup>4,16</sup> (*Strong Recommendation*)
- A multidisciplinary team to care for gastric cancer patients may include surgeons, medical oncologists, radiation oncologists, radiologists, pathologists, gastroenterologists, general practitioners in oncology, nurses, social workers, palliative care specialists, and dieticians.<sup>4</sup> (*Strong Recommendation*)

### *Qualifications and Key Evidence for Recommendation 7*

- Due to the broad and complex nature of multidisciplinary treatments for gastric cancer, and given evidence that multidisciplinary management has been shown to increase the accuracy of diagnosis and treatment planning, the SSWG recommended multidisciplinary decision-making for gastric cancer surgical patients, after staging but before treatment (or re-treatment).<sup>4,16,17,18</sup>
- This recommendation is in alignment with the RAND/UCLA Panel approach to multidisciplinary care, which deemed the approach *necessary*.<sup>4</sup>

## Structural Criteria

### Facility Criteria

#### Surgical Facility/Hospitals

##### *Recommendation 8*

- Gastric cancer surgery should be performed in a centre with sufficient support to prevent or manage complications (e.g., interventional radiology, anesthesia, Level 1 intensive care unit (ICU)).<sup>4</sup> (*Strong Recommendation*)
- When appropriate, non-emergent curative intent resections should be performed in hospitals with an annual volume of gastric cancer resections >15 cases/year.<sup>4</sup> (*Weak Recommendation*)

##### *Qualifications and Key Evidence for Recommendation 8*

- Four systematic reviews (including two meta-analyses), which addressed hospital volumes for gastric cancer surgery and the effects on survival outcomes, were included in this review. The SSWG found that the quality of the evidence across the available systematic reviews was subject to high levels of heterogeneity in study design, hospital volumes definitions, case mix adjustments, tumour stage and other variables.
- One meta-analysis (13 studies) found that high-volume hospitals ( $\geq 10$ -13 gastric cancer-related operations/year) had a protective effect on unadjusted procedure-related mortality compared to low-volume hospitals (<10 gastric cancer-related operations/year) (OR 0.73; 95% CI, 0.65-0.81).<sup>19</sup> The results of another meta-analyses demonstrated a statistically significant inverse association between hospital volume and short-term mortality in 14/20 observational studies, and 2/20 for long-term mortality.<sup>20</sup> One systematic review found better outcomes in high-volume hospitals in primarily retrospective studies, but the effect was limited when evaluated in prospective studies.<sup>21</sup> Another systematic review of nonrandomized studies found a benefit to high volume hospitals for most large studies (>5000 patients), but not in smaller studies.<sup>22</sup>
- Given the apparent benefits associated with higher hospital volumes on gastric cancer surgical short-term mortality, yet recognizing the complexity of associated variables, the SSWG felt that management of non-emergent gastric surgery in higher volume centres warrants consideration. The SSWG felt it was appropriate to endorse the RAND/UCLA Panel approach supporting non-emergent gastric cancer surgeries in facilities with >15 cases/year (*appropriate*), and in facilities with the capacity to prevent and manage complications (*necessary*).<sup>4</sup>

## Surgeon Criteria

### Training and Case Volume

#### *Recommendation 9*

- Gastric cancer surgery performed by a surgeon experienced in gastric cancer management is preferred.<sup>4</sup> (*Weak Recommendation*)

#### *Qualifications and Key Evidence for Recommendation 9*

- Four systematic reviews were included that addressed surgeon case volumes or experience and patient outcomes.<sup>19,20,21,22</sup> All four systematic reviews showed a benefit to higher surgeon case volume or experience, and short- and long-term outcomes; however, the results were not consistent across all studies. Heterogeneity across variables in the included studies, particularly around volume definitions makes their application less reliable as quality indicators in gastric cancer surgery.
- The SSWG felt that despite the limitations, the benefits associated with improved outcomes relative to surgeon case volumes were important. The working group therefore chose to endorse the above recommendation of gastric cancer management experience and a minimum case volume from the RAND/UCLA approach.<sup>4</sup>

## Quality Indicators

Quality indicators were identified based on those that the working group identified primarily as *strong recommendations*. Additional quality indicators were included if the recommendations were considered measurable and useful for future evaluation purposes. Nineteen quality indicators were identified, which can be used to prospectively or retrospectively monitor both quality of process, the suitability of the setting, and subsequent outcomes in gastric cancer surgical care (see Table 1 – Quality Indicators for Gastric Cancer Surgery). Monitoring and evaluation of quality indicators allows for feedback to healthcare providers and organizations, as well as the opportunity to develop strategies and targeted actions to improve quality and outcomes for gastric cancer surgical care.

**TABLE 1 – QUALITY INDICATORS FOR GASTRIC CANCER SURGERY**

Staging	Indicator	Strength of Recommendation (if applicable)	Type of Indicator
Gastric QI-1	Preoperative CT of abdomen/pelvis/chest for staging.	<i>Strong</i>	Process
Gastric QI-2	Diagnostic laparoscopy with peritoneal washing performed before initiating treatment.	<i>Strong</i>	Process
<b>Multidisciplinary Care</b>			
Gastric QI-3	Patients diagnosed with gastric cancer discussed at a multidisciplinary team meeting following staging, but before treatment initiation.	<i>Strong</i>	Process
Gastric QI-4	Patients with non-curative gastric cancer who received palliative care.	<i>Strong</i>	Process
Gastric QI-5	Patients discussed at a multidisciplinary team meeting prior to consideration for surgical re-excision.	<i>Strong</i>	Process
<b>Organization</b>			
Gastric QI-6	Patients treated for gastric cancer in a centre with sufficient supports to prevent or manage complications (i.e. interventional radiology, anesthesia, Level 1 ICU).	<i>Strong</i>	Setting
Gastric QI-7	Patient treated for non-emergent curative intent gastric cancer resection in a higher volume (>15 resections/year) hospital.	<i>Weak</i>	Setting

Surgery			
Gastric QI-8	Assessment of $\geq 16$ lymph nodes for staging of curative resected gastric cancer.	<i>Strong</i>	Process
Gastric QI-9	Intraoperative frozen sections analysis of margins in curative-intent resections.	<i>Strong</i>	Process
Gastric QI-10	D1 dissection performed in patient with T1N0 cancer or with significant comorbidities.	<i>Strong</i>	Process
Gastric QI-11	D2 dissection performed without routine distal pancreatectomy and splenectomy.	<i>Strong</i>	Process
Gastric QI-12	Patients with an R0 resection following surgery.	<i>Strong</i>	Outcome
Evaluation			
Gastric QI-13	Patient gastric cancer stage.		Baseline
Gastric QI-14	Patient with significant comorbidities.		Baseline
Gastric QI-15	Gastric resection mortality rate (30 days).		Outcome
Gastric QI-16	Gastric cancer recurrence rate.		Outcome
Gastric QI-17	Patient 5-year overall survival.		Outcome
Gastric QI-18	Patient 5-year survival by stage.		Outcome
Gastric QI-19	Gastrectomy for palliation in patients with metastatic disease.		Outcome

## Implementation

These evidence-informed recommendations and associated indicators provide a framework for a quality initiative for gastric cancer surgery in B.C. This work is in parallel to some of the quality assurance initiatives in GI care including the *European Registration of Cancer Care (EURECCA) Upper GI Project*, and the *Belgian Health Care Knowledge Centre* quality initiatives for upper GI cancer.<sup>23,24</sup>

Implementation of these recommendations at a hospital and health authority level will allow for the standardization of gastric cancer surgical care, which is expected to improve quality and decrease variation across regions. Inclusion of quality indicators in surgical reporting in a prospective manner creates the potential for evaluation of gastric cancer surgical quality including the delivery and/or setting of care, and setting-specific surgical outcomes in B.C. Knowledge translation at a health provider, organization, and regional level provides opportunities to provide valuable feedback, as well as the opportunity to quantitatively inform future recommendations, with the ultimate goal of improving outcomes for gastric cancer patients.

## Renewal Cycle

The recommendations in this guideline are due to be updated every 5 years from the date of endorsement (page 2), or when new evidence becomes available that may change the recommendations, including but not limited to changes in benefits or harms of interventions, or new information on clinical outcomes.

Interim updates to evidence and/or recommendations that result in a change in recommended practice will be subject to a modified review process similar to the original development cycle. Updates that are practical and/or editorial and do not change recommendations for practice will be made at the discretion of the working group chair and/or the SSWG. Interim updates will be documented and will not result in a change to the recommended renewal cycle.

## Abbreviations

AGREE – Appraisal of Guidelines for Research & Evaluation  
CCO – Cancer Care Ontario  
CI – confidence interval  
CPGs – clinical practice guidelines  
CT – computerized tomography  
DFS – disease-free survival  
DSS – disease-specific survival  
EURECCA – European Registration of Cancer Care  
EUS – endoscopic ultrasonography  
GI – gastrointestinal  
GRADE – Grading of Recommendations Assessment, Development and Evaluation  
HR – hazard ratio  
ICU – intensive care unit  
OR – odds ratio  
OS – overall survival  
PET – positron emission tomography  
RCT – randomized controlled trial(s)  
RFS – recurrence-free survival  
RR – relative risk  
SSWG – Surgical Standards Working Group

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