MEDICAL PRACTICE

Use of biologics for inflammatory bowel disease in Hong Kong: consensus statement

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Objective With the increasing use of biologics in patients with inflammatory bowel disease, the Hong Kong IBD Society developed a set of consensus statements intended to serve as local recommendations for clinicians about the appropriate use of biologics for treating inflammatory bowel disease.

Participants The consensus meeting was held on 9 July 2011 in Hong Kong. Draft consensus statements were developed by core members of the Hong Kong IBD Society, including local gastroenterologists and colorectal surgeons experienced in managing patients with inflammatory bowel disease.

Evidence Published literature and conference proceedings on the use of biologics in management of inflammatory bowel disease, and guidelines and consensus issued by different international and regional societies on recommendations for biologics in inflammatory bowel disease patients were reviewed.

Consensus process Four core members of the consensus group drafted 19 consensus statements through the modified Delphi process. The statements were first circulated among a clinical expert panel of 15 members for review and comments, and were finalised at the consensus meeting through a voting session. A consensus statement was accepted if at least 80% of the participants voted "accepted completely" or "accepted with some reservation".

Conclusions Nineteen consensus statements about inflammatory bowel disease were generated by the clinical expert panel meeting. The statements were divided into four parts which covered: (1) epidemiology of the disease in Hong Kong; (2) treatment of the disease with biologics; (3) screening and contra-indications pertaining to biologics; and (4) patient monitoring after use of biologics. The current statements are the first to describe the appropriate use of biologics in the management of inflammatory bowel disease in Hong Kong, with an aim to provide guidance for local clinical practice.

Introduction

Inflammatory bowel disease (IBD) consists of Crohn's disease (CD) and ulcerative colitis (UC). Crohn's disease is a multisystem disorder with specific clinical and pathological features characterised by focal, asymmetrical, transmural, and occasionally granulomatous inflammation, primarily affecting the gastro-intestinal tract. Ulcerative colitis, on the other hand, is a disease with a predilection for the rectum and colon with continuous and superficial inflammation of the colonic mucosa. In the past, the two diseases were considered rare in the Chinese population. Recent data, however, show that for unknown reasons they are increasing in our locality.[1,2]

There has been a paucity of studies on the management of IBD from the Asia-Pacific region including Hong Kong, especially on the use of biologics.[3-7] Most of the efficacy and safety data about these novel agents have been obtained in western studies. However, it has been suggested that genetic susceptibilities in Asian IBD patients differ from those in Caucasians.[8] Previous studies also reported ethnic differences in the clinical phenotypes and complications of these disorders.[9] It is therefore likely that the efficacy and side-effects of biologics in Asians and Caucasians may differ, which suggests that standard

香港生物製劑治療炎症性腸病的共識聲明

目的 隨着使用生物製劑治療炎症性腸病日益普遍，《香港炎症性腸病學會》制定了一套有關正確使用生物製劑治療炎症性腸病的共識聲明，為本地醫生提供建議作參考用。

參與者 於2011年7月9日舉行共識會議。由《香港炎症性腸病學會》的主要成員草擬共識聲明，成員包括對於處理炎症性腸病甚具經驗的胃腸學醫生及結直腸外科醫生。

證據 搜尋關於使用生物製劑治療炎症性腸病的文獻及會議論文撮要，以及國際及地區性學會發出有關的建議和指引。

綜述過程 《香港炎症性腸病學會》的四位主要成員於會議前透過修正式德菲法（Delphi process）草擬了19項共識，並將草稿給予15位臨床專家小組成員傳閱及徵求意見，最後通過投票制定了共識聲明的最終版本。每項聲明均須符合最少八成的小組成員「完全贊成」或「雖有保留但仍贊成」才可被接納。

結論 臨床專家小組成員發出了19項的共識。共識聲明分為以下四部份：炎症性腸病的流行病學、炎症性腸病的生物製劑治療、與生物製劑有關的篩選及禁忌、和使用生物製劑後對病人的監察。這份共識聲明首次為本地醫生提供有關正確使用生物製劑治療炎症性腸病的建議作參考指引之用。

therapies/treatment guidelines for IBD patients in western countries may not be applicable to Asian counterparts. Owing to the increasing patient load and availability of biologics, clinicians should become updated on their appropriate use in treating patients with IBD, especially from a local perspective.

For this reason, the Hong Kong IBD Society organised a consensus meeting with the goal of developing a set of consensus statements offering guidance on the appropriate use of biologics in managing IBD patients in Hong Kong.

Methods

The consensus meeting was held on 9 July 2011 in Hong Kong. Members of the Hong Kong IBD Society including local gastroenterologists and colorectal surgeons experienced in managing affected patients were invited. Prior to the meeting, four core members of the consensus group drafted 19 consensus statements through the modified Delphi process,[10] which were circulated to all participants for review and comments. The statements were divided into four parts which covered: (1) epidemiology of IBD in Hong Kong; (2) treatment of IBD with biologics; (3) screening and contra-indications of biologics; and (4) monitoring after use of biologics.

During the meeting, core members of the consensus group reviewed and summarised the literature on these four topics. After the presentation, panel members (consisting of 15 local clinical experts) voted on the statements pertaining to each topic. Voting was anonymous. A consensus statement was accepted if at least 80% of participants voted "A: accept completely" or "B: accept with some reservation" (Table). Assessment for each consensus statement during the voting session included categorisation of evidence and classification of recommendations, which were modified from the Canadian Task Force on Periodic Health Examination (Table).[5]

Results

Epidemiology of inflammatory bowel disease in Hong Kong

Statement 1: The incidence of inflammatory bowel disease is rising in Hong Kong

Level of agreement: A-73%, B-27%, C-0%, D-0%, E-0%

(Quality of evidence: II-2; Classification of recommendation: B)

Inflammatory bowel disease was once considered a rare disease in Hong Kong. However, local epidemiologic studies reported a 3-fold increase in the incidence of CD and a 6-fold increase in the incidence of UC.[1,2] The annual incidence of CD and UC

TABLE. The grading system for each consensus statement during the voting session

Choice	Quality of evidence	Classification of recommendation	Voting (on recommendation)
A	(I) Evidence obtained from at least 1 randomised controlled trial	There is good evidence to support the statement	Accept completely
B	(II-1) Evidence obtained from well-designed control trials without randomisation	There is fair evidence to support the statement	Accept with some reservation
C	(II-2) Evidence obtained from well-designed cohort or case-control study	There is poor evidence to support the statement but recommendation made on other ground	Accept with major reservation
D	(II-3) Evidence obtained from comparison between time or places with or without intervention	There is fair evidence to refute the statement	Reject with reservation
E	(III) Opinion of respected authorities based on clinical experience and expert committees	There is good evidence to refute the statement	Reject completely

is estimated to be 1.0 per 100 000[1] and 2.1 per 100 000,[2] respectively. The median age at diagnosis of CD was 30 years with a male-to-female ratio of 2:1.[11] The proportions of CD patients with non-stricturing, non-penetrating (B1), stricturing (B2), and penetrating (B3) disease at diagnosis as determined by the Montreal classification were 67%, 30%, and 3%, respectively.[12] Half of the patients were diagnosed with ileocolic disease (L3) at presentation.[11] For UC, the median age at diagnosis was 37 years with a male-to-female ratio of 1:1.[2] The ratio of extensive colitis, left-sided colitis, and ulcerative proctitis were 4:3:3.[2]

Statement 2: Utilisation of biological therapies in the treatment of inflammatory bowel disease needs to be optimised in Hong Kong

Level of agreement: A-40%, B-60%, C-0%, D-0%, E-0%
(Quality of evidence: III; Classification of recommendation: C)

In Hong Kong, corticosteroids remain one of the most commonly prescribed treatment options for IBD patients; 58% of CD and 54% of UC patients had taken corticosteroids.[13] However, approximately one third of them progressed to corticosteroid-dependent disease after 1 year. Although there is accumulating clinical evidence suggesting that anti–tumour necrosis factors (anti-TNFs) are highly efficacious in the treatment of IBD, their use is limited in Asia as compared to western countries. Based on a study conducted in a teaching hospital in Hong Kong, only 11% of CD patients and 1% of UC patients had received anti-TNF therapy.[3] A recent survey of current IBD patient management in different parts of Asia including Hong Kong found that no IBD specialists considered anti-TNFs as first-line treatment for CD. Only 20% of them considered anti-TNFs as the second choice. Less than 15% would choose them for the management of UC.[4] The limited use of anti-TNFs in Asia may be due to various factors, including high costs, a lack of insurance reimbursement, and concern over opportunistic infections.[4,5,14]

Statement 3: Current access to biological therapies remains limited in Hong Kong mainly due to high cost

Level of agreement: A-40%, B-53%, C-7%, D-0%, E-0%
(Quality of evidence: III; Classification of recommendation: C)

There has been a lack of local cost-utility analyses on biologics, but in the panel's opinion, from a public sector perspective the cost of biological agents is considered to be high, and so they have to be largely self-financed. However, funding is available for those who are suffering from moderate-to-severe CD (ie CDAI [Crohn's Disease Activity Index] ≥300, or active fistulating disease) and cannot afford the medications. Cost remains a major obstacle discouraging patients from choosing biological agents as a therapeutic option.

Treatment of inflammatory bowel disease with biologics

Statement 4: Biologics are effective for the induction and maintenance of remission in patients with active luminal Crohn's disease

Level of agreement: A-93%, B-7%, C-0%, D-0%, E-0%
(Quality of evidence: I; Classification of recommendation: A)

Overwhelming data in the literature support the use of anti-TNFs (infliximab, adalimumab and certolizumab) for patients with luminal CD. The ACCENT I trial (A Crohn's disease Clinical trial Evaluating infliximab in a New long-term Treatment regimen I) showed that at week 30, patients with moderate-to-severe CD treated with infliximab (5 or 10 mg/kg) were more likely to sustain clinical remissions than those treated with placebo (odds ratio=2.7; 95% confidence interval, 1.6-4.6).[15] In the CHARM (Crohn's trial of the fully Human antibody Adalimumab for Remission Maintenance) study, remission rates were significantly higher in adalimumab groups (40 mg every other week and 40 mg weekly) compared to the placebo group at week 56 (36% and 41% vs 12%, respectively).[16] The PRECiSE 2 (The Pegylated antibody fRagment Evaluation in Crohn's disease: Safety and Efficacy 2) trial showed that patients who had responded to 6 weeks of open-label induction treatment with certolizumab 400 mg were more likely to maintain a response at week 26 when continued on certolizumab pegol than if switched to placebo (63% vs 36%).[17] Recent data also suggest that early use of biologics (ie the top-down approach) may be more effective in preventing disease progression.[18-20]

Statement 5: Biologics should be considered in patients with active fistulising Crohn's disease, particularly in those with complex perianal fistulising diseases

Level of agreement: A-80%, B-20%, C-0%, D-0%, E-0%
(Quality of evidence: I; Classification of recommendation: A)

One of the earliest studies on anti-TNFs showed that after three doses of infliximab 5 mg/kg, 55% of patients with fistulising CD achieved closure of draining abdominal or perianal fistulae.[21] The pivotal ACCENT II maintenance trial also indicated that systemic treatment with infliximab 5 mg/kg every 8 weeks was superior to placebo for closure of draining fistulas at week 54 (36% vs 19%).[22] Another long-term study with infliximab showed that about one third of patients had healed fistulae after 5 years of infliximab treatment.[23] The CHARM study demonstrated that at week 56, fistula closure was evident in about one third of CD patients receiving adalimumab.[16]

Statement 6: Biologics are effective for the induction of clinical remission in patients with moderately to severely active ulcerative colitis who failed treatment with corticosteroids and/or immunosuppressants

Level of agreement: A-53%, B-40%, C-0%, D-7%, E-0%
(Quality of evidence: I; Classification of recommendation: A)

Infliximab has been used in the treatment of patients with moderate-to-severe UC who failed conventional treatment. In the randomised placebo-controlled ACT (the Active ulcerative Colitis Trials) studies, patients with moderate-to-severe UC who had failed or were intolerant to corticosteroids (ACT-1 and -2) or thiopurines (ACT-1) were randomised to infliximab (5 or 10 mg/kg), or to placebo for 1 year. In the infliximab 5 mg/kg group, remission (Mayo score ≤2) was achieved in 39% (ACT-1) and 34% (ACT-2) at week 8, and 34% (ACT-1) and 26% (ACT-2) at week 30, respectively (all P≤0.003 compared to placebo).[24] In patients with acute severe UC refractory to intravenous steroids, a recent study showed that infliximab was non-inferior to cyclosporin.[25] The response rates at day 7 were 84% for cyclosporin and 86% for infliximab, respectively. At day 98, 10 out of 55 patients treated with cyclosporin and 13 out of 56 patients treated with infliximab underwent colectomy.

Statement 7: Recognition of adverse prognostic factors should lead to early use of biologics in Crohn's disease

Level of agreement: A-33%, B-53%, C-13%, D-0%, E-0%
(Quality of evidence: II-1; Classification of recommendation: A)

Severe adverse prognostic factors such as young age, presence of perianal lesions, extensive small bowel disease, stricturing disease, and deep colonic ulcers have been associated with increased risk of colectomy and penetrating complications.[26] Patients without adverse prognostic factors could be considered for conventional drugs with rapid step-up to anti-TNF agents in those who fail treatment. In patients with adverse prognostic factors, anti-TNF therapy with or without immunosuppressive drugs should be considered early.[27]

Statement 8: For maintenance treatment with biologics in Crohn's disease patients, scheduled maintenance regimen is superior to episodic regimen

Level of agreement: A-73%, B-20%, C-7%, D-0%, E-0%
(Quality of evidence: I; Classification of recommendation: A)

The ACCENT I trial showed that the scheduled maintenance group (infliximab 5 mg/kg at weeks 0, 2, and 6 followed by 5 mg/kg or 10 mg/kg every 8 weeks) had higher response and remission rates compared to those receiving episodic therapy.[28] Resorting to hospitalisation and surgery also decreased to a greater extent in the group scheduled to maintenance infliximab group compared to those on episodic therapy.[29] In a randomised open-label study in paediatric CD patients, those receiving scheduled infliximab therapy achieved a higher remission rate than those receiving episodic therapy (83% vs 61% respectively).[30]

Statement 9.a: Biologics combined with thiopurine is the most effective approach in inducing remission and in achieving mucosal healing in Crohn's disease

Level of agreement: A-80%, B-20%, C-0%, D-0%, E-0%
(Quality of evidence: I; Classification of recommendation: A)

In the recent SONIC (Study Of biologic and immunomodulator Naive patients In Crohn's disease) trial, the steroid-free remission rate was higher in those on the combination of infliximab plus azathioprine compared to the infliximab-alone and azathioprine-alone arms. The respective rates at week 26 were 57%, 44% and 30%, and at week 50 they were 72%, 61% and 55%.[31] At week 26, mucosal healing occurred in 44% of the patients receiving combination therapy, as compared to 30% in those receiving infliximab alone and 16.5% in those on azathioprine alone.[31]

Statement 9.b: The risk and benefit of combination therapy with biologics and thiopurine should be considered in each individual patient

Level of agreement: A-33%, B-53%, C-13%, D-0%, E-0%
(Quality of evidence: II-2/III; Classification of recommendation: C)

In young males, fatal cases of hepatosplenic T cell lymphoma have been reported in patients on combination infliximab and thiopurine, or thiopurine alone, but not in those on infliximab alone.[32] Therefore, the use of the combination therapy with biologics and thiopurine monotherapy should be appraised carefully in each patient, and the risks and benefits need to be discussed.

Statement 10: In Crohn's disease patients who have lost response to a biologic and after exclusion of complications, a dose-intensification strategy (increase in dose or a decrease in dosing interval) or switching to a different biologic can be effective

Level of agreement: A-27%, B-60%, C-13%, D-0%, E-0%
(Quality of evidence: II-1; Classification of recommendation: B)

About one third of patients treated with biologics lose responsiveness at 1 year. In cases of secondary loss of response, it is important to confirm active CD and exclude complications such as infections. Following that, initiation of a short course of corticosteroids, increase in dosage or reduction in the dosing interval of anti-TNFs, or switching to a different biologic can be considered.[27] However, no controlled data or head-to-head comparisons are available to indicate which method is superior. In the opinion of panel members, dosage increase or reduction of the dosing interval of current anti-TNF therapy should be attempted before switching to a different biologic.

Statement 11: Biologics are effective for inducing and maintaining remission in paediatric Crohn's disease

patients with moderate-to-severe disease who are refractory to or intolerant of conventional therapy

Level of agreement: A-67%, B-27%, C-7%, D-0%, E-0%

(Quality of evidence: I; Classification of recommendation: A)

Currently, first-line induction or remission therapy of CD continues to depend on steroids or exclusive enteral nutrition; the latter being associated with fewer side-effects, reversal of growth failure and mucosal healing.[33] Biologics are also effective in inducing and maintaining responses and remissions in paediatric CD. In the REACH (Randomized, multicenter, open-label study to Evaluate the safety and efficacy of Anti-TNF alpha Chimeric monoclonal antibody in pediatric subjects with moderate to severe Crohn's disease) trial, 88% of children with moderate-to-severe disease responded to infliximab and 59% achieved clinical remission at week 10.[34] At 3 years, approximately 80% of patients had no-to-mild disease activity, and patients with ≥1-year delay in bone age at baseline showed improvement in height.[35] For adalimumab, a prospective study showed a 91% response rate and 65% remission rate at 1 year.[36] In a retrospective study, 70% and 42% of children with moderate-to-severe CD previously treated with infliximab achieved a clinical response and steroid-free remission on adalimumab at 1 year, respectively.[37]

Screening and contra-indications of biologics

Statement 12: Biologics may not be beneficial in patients with fibrostenotic Crohn's disease

Level of agreement: A-27%, B-73%, C-0%, D-0%, E-0%

(Quality of evidence: II-1; Classification of recommendation: B)

According to the London Position Statement, patients with fibrostenotic CD without objective evidence of active inflammation (based on elevated C-reactive protein levels, endoscopy, or radiographic assessment) rarely benefit from biological therapy.[32] Strictures are not an absolute contra-indication to anti-TNF therapy, but if there is evidence of pre-stenotic dilatation, the fibrotic component is less likely to be reversed by medical therapy and for most patients endoscopic dilatation, stricturoplasty, or stricture resection may be deemed necessary.[32]

Statement 13: Patients with active infection should be treated (eg abscess should be drained) before considering the use of biologics

Level of agreement: A-67%, B-27%, C-7%, D-0%, E-0%

(Quality of evidence: III; Classification of recommendation: C)

For obvious reasons, patients with an active infection should not receive biological therapy until it is under control.[32] Any abscess needs to be drained. Also, patients who have received live vaccines should not receive biological therapy for at least 3 months.[32]

Statement 14.a: All inflammatory bowel disease patients should be screened for hepatitis B virus status prior to initiation of biologics

Level of agreement: A-87%, B-13%, C-0%, D-0%, E-0%

(Quality of evidence: II-2; Classification of recommendation: B)

Patients with IBD undergoing anti-TNF treatment have an increased risk of hepatitis B virus (HBV) reactivation. Liver dysfunction is more frequent in HBV carriers treated with immunosuppressive agents; 36% of whom suffer from liver failure.[38] Therefore, HBV screening (checking hepatitis B surface antigen [HBsAg] and anti-HBs antibody) is necessary at the time of diagnosing CD, particularly in Hong Kong. Close surveillance of liver function is necessary prior to biological therapy,[39] and monitoring should continue for 6 to 9 months after cessation of anti-TNF therapy. Levels of HBV-DNA should be monitored in patients found to be HBsAg-positive.

Statement 14.b: Initiation of antiviral therapy should be individualised

Level of agreement: A-40%, B-60%, C-0%, D-0%, E-0%

(Quality of evidence: III; Classification of recommendation: C)

According to the European Crohn's and Colitis Organisation recommendations on HBV, to avoid a hepatitis B flare, any IBD patients who are HBV carriers should receive pre-emptive therapy with antiviral agents prior to receiving immunomodulator therapy, regardless of the degree of viraemia.[40] In terms of optimal strategy, there is no evidence on whether non-selective pre-emptive antiviral prophylaxis, selective antiviral prophylaxis in high-risk groups, or close surveillance and early antiviral treatment for progressive viraemia is the best treatment. Antiviral therapy for HBV should therefore be individualised. For hepatitis C virus (HCV), there is little evidence that treatment with biologics interferes with HCV activity and routine prophylactic treatment is generally not recommended.[41]

Statement 15: Screening for tuberculosis by history, physical examination, chest X-ray, and tuberculin skin test is mandatory prior to the initiation of biologics. Biologics should be postponed and anti-tuberculosis chemoprophylaxis or treatment should be given to patients with latent or active tuberculosis

Level of agreement: A-73%, B-27%, C-0%, D-0%, E-0%

(Quality of evidence: II-2; Classification of recommendation: B)

Anti-TNF therapy increases the risk of tuberculosis (TB) by about 4-fold, with a median onset at about 12 weeks.[42] Therefore, a thorough TB screening by history, physical examination, chest X-ray, and tuberculin skin testing should be performed prior to initiating therapy (Fig).[42] Due to frequent false-negative tuberculin tests, the use of gamma

interferon-based assays may help to increase their sensitivity and specificity. High vigilance must be maintained for reactivation of TB in patients receiving anti-TNF therapy, and close monitoring of patients should continue for 6 to 9 months after cessation of biologics. Patients considered at high risk for latent TB should receive chemoprophylaxis (isoniazid alone for 6-9 months, rifampicin alone for 4 months, or isoniazid and rifampicin for 3 months). Chemoprophylaxis should be given for at least 1 month before starting anti-TNF therapy.[42]

Statement 16: Patients with a history of solid cancer or lymphoproliferative disease should not receive biologics if there are other options available

Level of agreement: A-7%, B-80%, C-13%, D-0%, E-0%

(Quality of evidence: III; Classification of recommendation: C)

Although there are few convincing data on the risk of anti-TNF therapy in patients with a history of previous malignancy, the 2009 London Position Statement stated that such patients or those with prior lymphoproliferative disorder should not be treated with anti-TNF if other options exist.[32] A recent literature review concluded that because of the potential for progression, anti-TNF therapy is an absolute contra-indication in patients who have had a solid cancer or haematological malignancy diagnosed within the past 5 years.[39] On the other hand, cancers diagnosed more than 5 years earlier and considered cured after treatment may be regarded as having a relative contra-indication only.[39]

Monitoring after use of biologics

Statement 17: Patients should be closely monitored for infective complications after treatment with biologics, in particular mycobacterial and other opportunistic infections. Close liaison with infectious disease specialists is recommended

Level of agreement: A-33%, B-60%, C-7%, D-0%, E-0%

(Quality of evidence: III; Classification of recommendation: B)

Biologics have been reported to increase the risk of mycobacterial and other opportunistic infections such as listeriosis, nocardiosis, and invasive aspergillosis.[43] In patients with any suspected infection, close liaison with infectious disease specialists is recommended after the initiation of treatment with biologics.

Statement 18: Patients should be observed for rare but severe cardiac and neurological complications. Prompt discontinuation of biologics is essential if heart failure develops or demyelinating disease is suspected

Level of agreement: A-40%, B-60%, C-0%, D-0%, E-0%

(Quality of evidence: II-3/III; Classification of recommendation: C)

There is a lack of controlled trials in assessing the risk of anti-TNFs in patients with heart failure, but they are contra-indicated in patients with class III-IV congestive heart failure due to sporadic case reports showing an increased risk of death.[44] New onset or exacerbation of central nervous system demyelinating disorders has also been reported with the use of anti-TNFs.[44] A high level of vigilance must therefore be maintained for patients on anti-TNF therapy with pre-existing or recent heart failure or a demyelinating disorder; such therapy should cease immediately if any exacerbation is suspected.

Statement 19: High vigilance should be exercised regarding the risk of hepatosplenic T-cell lymphoma

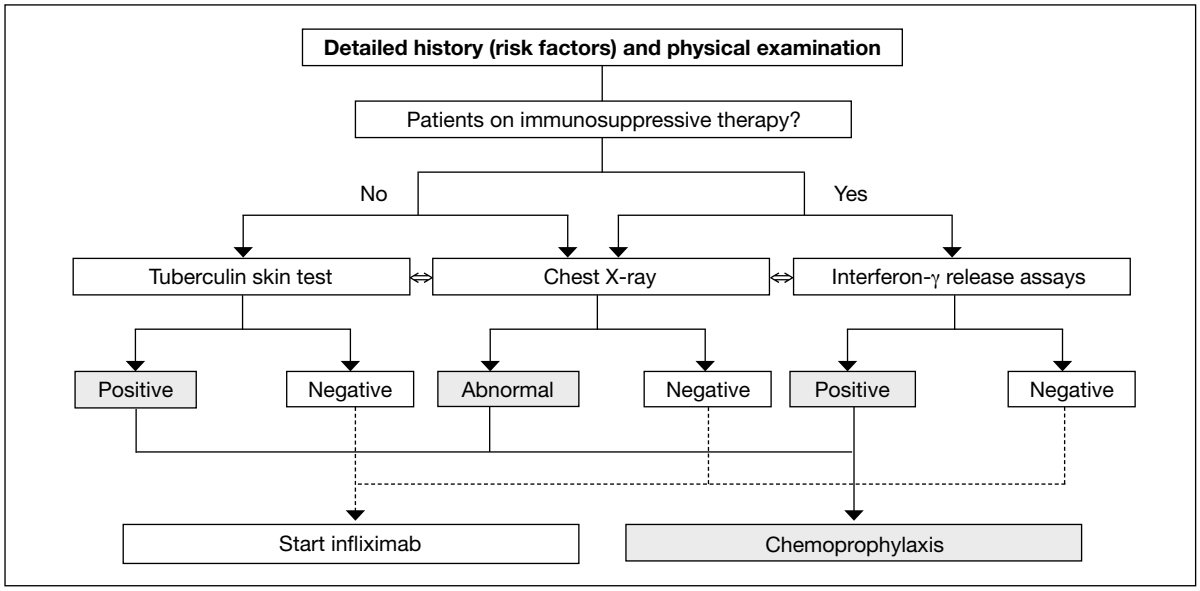

FIG. Recommended strategy for tuberculosis screening and treatment in patients with inflammatory bowel disease
Adapted from Papa et al[39]

in young patients receiving concomitant thiopurine therapy and anti–tumour necrosis factor agents

Level of agreement: A-67%, B-33%, C-0%, D-0%, E-0%

(Quality of evidence: II-2; Classification of recommendation: B)

Although there has been no convincing data proving the risk of cancer in IBD patients undergoing anti-TNF treatment, hepatosplenic T-cell lymphoma (a rare form of non-Hodgkin's lymphoma) was reportedly associated with the concomitant use of anti-TNFs and azathioprine.[43] A link between anti-TNFs and lymphomas or other malignancies cannot be completely excluded.

Conclusions

Although anti-TNFs have been available for more than a decade, their use in Hong Kong remains limited and local clinicians may still be unfamiliar with them. This is the first consensus statement on the appropriate use of biologics in the treatment of IBD in Hong Kong. We have attempted to address a variety of topics including the target patients and appropriate use of biologics, contra-indications and precautions with the use of biologics, and issues related to patient monitoring. The current paper also summarises the recent clinical efficacy and safety data of different anti-TNFs for treating various forms of CD and UC, which provides supporting evidence for local clinicians to treat their patients with biologics. Recommendations on timing of initiation of biologics, dosing schedules, and drug combinations have also been indicated to promote their proper use to achieve optimal outcomes. However, due to the paucity of local or even any Asian data, many of these recommendations are based on western published data. It is possible that treatment responses to biologics may vary in local Chinese IBD patients, due to differences in drug pharmacokinetics and phenotypic and genotypic characteristics of the disease between Asian and western patients. Hence, more local experience and data are necessary to provide a more evidence-based local guideline on the treatment for our patients. While agreement exists pertaining to the messages conveyed in the consensus statements, it is important to recognise that the final decision on the therapeutic approach needs to be tailored to fit individual patient needs.

These consensus statements aim to provide local clinical experts with information about the benefits and risks associated with biological therapies for patients with IBD, and serve as a reference for their appropriate use.

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