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CLINICAL PRACTICE GUIDELINES

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World Association for Bronchology and Interventional Pulmonology (WABIP) guidelines on airway stenting for malignant central airway obstruction

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Abstract

Malignant Central Airway Obstruction (MCAO) encompasses significant and symptomatic narrowing of the central airways that can occur due to primary lung cancer or metastatic disease. Therapeutic bronchoscopy is associated with high technical success and symptomatic relief and includes a wide range of airway interventions including airway stents. Published literature suggests that stenting practices vary significantly across the world primarily due to lack of guidance. This document aims to address this knowledge gap by addressing relevant questions related to airway stenting in MCAO. An international group of 17 experts from 17 institutions across 11 countries with experience in using airway stenting for MCAO was convened as part of this guideline statement through the World Association for Bronchology and

Udit Chaddha and Abhinav Agrawal contributed equally to this study.

Interventional Pulmonology (WABIP). We performed a literature and internet search for reports addressing six clinically relevant questions. This guideline statement, consisting of recommendations addressing these six PICO questions, was formulated by a systematic and rigorous process involving the evaluation of published evidence, augmented with expert experience when necessary. Panel members participated in the development of the final recommendations using the modified Delphi technique.

KEYWORDS
airway stenting, complications, malignant central airway obstruction, mechanical ventilation, mortality, quality of life, surveillance

INTRODUCTION

Malignant Central Airway Obstruction (MCAO) is defined as a significant and symptomatic narrowing of the trachea, mainstem bronchi or the bronchus intermedius by a neoplastic process. While MCAO can be due to metastasis from various extrathoracic cancers, it is mainly seen in primary lung cancer. The estimated prevalence of MCAO at the diagnosis of lung cancer is 13%, with an additional 5% of patients developing it during follow-up.[1] Airway invasion from oesophageal or thyroid cancer, lymphoma or metastasis from extra-thoracic malignancies may also cause MCAO. While the exact incidence of MCAO in these malignancies remains unknown, published data suggest that approximately 7%–37% of patients with bronchoscopically-treated MCAO have the obstruction due to non-primary lung cancer.[2–4] Patient presentations may range from mild shortness of breath to respiratory failure. Therapeutic bronchoscopy is associated with a high technical success in recanalizing a narrowed central airway, which often results in improvement of quality of life and symptoms.[2] Mechanistically, MCAO can be caused by tumour that is purely extrinsic and compressing the airway, endoluminal (or intrinsic) or of mixed morphology.[5] The type of obstruction affects bronchoscopic management, including the decision to stent.

Airway stents are primarily composed of silicone, metal or a combination of the two. Patients with symptoms or signs attributable to MCAO, such as dyspnoea, retained secretions or post-obstructive pneumonia, are usually stented after debulking endobronchial disease, if there is significant residual stenosis post debulking or if there is significant extrinsic airway compression. 'Significant' stenosis is usually defined as narrowing exceeding 50%,[6] however, flow dynamics studies suggest that pressure drops across a stenosis have only been noticed to significantly increase when the stenosis exceeds 70%.[7] Published literature suggest that stenting practices vary significantly across the world.[8] This is primarily due to the lack of guidance in this space. Despite over 30 years of experience with airway stenting,[6] there are no large randomized, comparative trials of airway stenting in MCAO, and there are no guidelines or consensus statements. Published data are largely from retrospective and single-centre studies.

This document aims to address this knowledge gap by addressing relevant questions related to airway stenting in MCAO. Throughout this manuscript, the use of the term "metallic" stents refers to either partially covered or covered metallic stents, and not uncovered stents. Our recommendations, while potentially relevant to other patient populations, may not be extrapolated to non-malignant CAO and to MCAO in children, as these are distinct clinical entities. Throughout this document, recommendations and remarks for airway stenting for MCAO pertain to only those in whom airway stenting is 'indicated': such as those who are symptomatic from MCAO[6,7] of extrinsic or mixed morphology or those with recurrent intrinsic MCAO. The management of MCAO of intrinsic morphology, with therapeutic bronchoscopy using ablative or mechanical techniques, is beyond the scope of this document. We acknowledge that decisions on airway stenting often involve a complex interplay of patient and procedure-dependent factors, and the extrapolation of our recommendations to a patient's unique scenario requires careful evaluation by qualified healthcare professionals.

METHODS

Literature search

We used expert opinion to formulate six questions relevant to the use of airway stenting for the management of patients with MCAO. Questions were formulated using the patient, intervention, comparison and outcome (PICO) format. An electronic search of Medline (PubMed interface) was executed employing

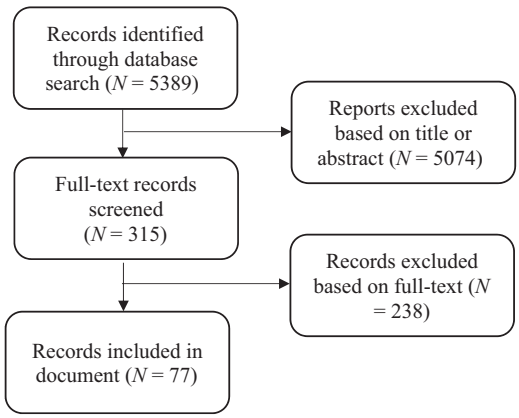

FIGURE 1 Prisma diagram.

TABLE 1 GRADE system.

Grade of recommendation	Risk/benefit	Quality of evidence
1A Strong Recommendation High Quality Evidence	Benefits clearly outweigh risks, or vice versa.	Consistent evidence from randomized, controlled trials or overwhelming evidence of some other form.
1B Strong Recommendation Moderate Quality Evidence	Benefits clearly outweigh risks, or vice versa.	Evidence from randomized, controlled trials with important limitations, or very strong evidence of some other form.
1C Strong Recommendation Low Quality Evidence	Benefits appear to outweigh risks, or vice versa.	Evidence from observational studies, unsystematic clinical experience or randomized, controlled trials with serious flaws.
2A Weak Recommendation High Quality Evidence	Benefits closely balanced with risks	Consistent evidence from randomized, controlled trials or overwhelming evidence of some other form.
2B Weak Recommendation Moderate Quality Evidence	Benefits closely balanced with risks, with some uncertainty in estimate of benefits and risks.	Evidence from randomized, controlled trials with important limitations, or very strong evidence of some other form.
2C Weak Recommendation Low Quality Evidence	Uncertainty in the estimates of benefits and risks; benefits may be closely balance with risks.	Evidence from observational studies, unsystematic clinical experience or randomized, controlled trials with serious flaws.

keywords "stent" OR "stenting" AND "airway obstruction" OR "tracheal stenosis" OR "bronchial stenosis" OR "laryngotracheal stenosis" OR "airway obstruction" AND "bronchoscopy" OR "airway obstruction" AND "stent" OR "malignant airway obstruction" OR "surveillance" OR "follow up" AND "airway obstruction" AND "stent," between 1985 and the present time (16 September 2022), applying an English language filter. A total of 5389 studies were returned using the above search strategy. Relevant studies including adult patients were evaluated based on the predefined questions. A total 315 full texts were evaluated, including manuscripts as well as their references, of which 77 articles were included in our final recommendations (Figure 1). We used the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to summarize relevant evidence and develop recommendations for clinical practice[9,10] (Table 1). We use expert consensus to grade recommendations for which no corresponding evidence was available. This approach incorporates two components—the strength of the recommendation and the certainty of the evidence. Summary of evidence tables for recommendations for the PICO questions is provided in Appendix in the Supporting Information.

Consensus methodology

A core writing group (UC, AA, JK, RO and SM) first drafted distinct statements and recommendations based on the table of evidence. The document was then circulated among all panel members, inviting both opinion and any additional recommendations. The panel included 17 pulmonologists with experience in using airway stenting for MCAO, from 17 different institutions in 11 countries. The document was revised based on comments from all members. The revised document was then shared with all members and subsequently discussed during a conference call with 88% participation. During the conference call, individual suggestions were reviewed and incorporated in real-time. The modified Delphi technique, a widely accepted method for the development of consensus among experts, was used to generate consensus.[11,12] As part of this process, a priori decision was made to conduct up to three rounds of anonymous voting or until consensus was achieved for each question, whichever came first. The survey incorporating the questions and revised recommendations was sent to all panel members. The panel independently and anonymously rated the appropriateness of the recommendations on a five-point Likert scale. Consensus was defined a priori as agreement at ≥70% (4 or 5 on the Likert scale) with a minimal response rate of 80%. The results of the survey were tallied and reported to the group. There was 100% survey participation from the members and consensus was achieved on all recommendations (Tables 2 and 3).

RESULTS

PICO Question 1

In patients with MCAO, does airway stenting improve quality of life and performance status, compared to no stenting?

Recommendation

In patients with symptomatic MCAO, we suggest that airways stenting be performed to improve quality of life or performance status (Grade 2B).

Remark

There is no difference in outcomes between covered metallic and silicone stents.

TABLE 2 Survey data assessing agreement with recommendation ($n = 17$).

Recommendations	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
PICO Question 1: In patients with MCAO, does airway stenting improve quality of life and performance status, compared to no stenting? Recommendation: In patients with symptomatic MCAO, we suggest that airways stenting be performed to improve quality of life or performance status (Grade 2B)				6 (35.3%)	11 (64.7%)
PICO Question 2: In patients with MCAO, does airway stenting impact mortality, compared to no stenting? Recommendation: In patients with MCAO, airway stenting can lead to improvement in survival and therefore, we suggest that it be pursued in the presence of attributable symptoms (Grade 2C)		1 (5.9%)		7 (41.2%)	9 (52.9%)
PICO Question 3: In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, does airway stenting impact liberation from mechanical ventilatory support? Recommendation: In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, we recommend airway stenting be considered, as it may lead to early liberation from ventilatory support (Grade 1C)				4 (23.5%)	13 (76.5%)
PICO Question 4: In patients with MCAO requiring airway stenting, do pulmonary hygiene measures reduce the incidence of stent-related complications, compared to no intervention? Recommendation: In patients with MCAO requiring airway stenting, we suggest that pulmonary hygiene measures be implemented to reduce the incidence of stent-related complications (Expert Consensus)			1 (5.9%)	7 (41.2%)	9 (52.9%)
PICO Question 5: In patients with MCAO requiring airway stenting, do routine surveillance bronchoscopies reduce the incidence of stent-related complications, compared to only symptom-driven bronchoscopies? Recommendation: In patients with MCAO requiring airway stenting, we suggest that surveillance bronchoscopies after stenting be performed to detect stent-related complications in asymptomatic patients (Grade 2C)		1 (5.9%)	3 (17.6%)	7 (41.2%)	6 (35.3%)
PICO Question 6: In patients with MCAO requiring airway stenting, does silicone stenting reduce the incidence of stent-related complications, compared to hybrid metallic stenting (fully or partially covered)? Recommendation: In patients with MCAO requiring airway stenting, we suggest that either silicone or hybrid metallic stents be used (Grade 2B)				8 (47.1%)	9 (52.9%)

Abbreviation: MCAO, malignant central airway obstruction.

Literature Review

Airway stenting in patients with attributable symptoms from MCAO, by re-establishing luminal patency, can lead to an improvement in these symptoms in greater than 90% of patients eligible for the intervention[13–20] The only randomized, controlled trial included 78 patients comparing silicone stenting to no stenting, and reported a longer duration of dyspnoea improvement in the stent group.[21] Possibly, due to being able to achieve a larger demonstrable change, patients with worse dyspnoea and a lower functional status may benefit more from an airway intervention.[2]

TABLE 3 PICO questions and recommendations.

PICO Question 1: In patients with MCAO, does airway stenting improve quality of life and performance status, compared to no stenting?
Recommendations:
- **In patients with symptomatic MCAO, we suggest that airways stenting be performed to improve quality of life or performance status (Grade 2B)**

Remark: *There is no difference in outcomes between covered metallic and silicone stents.*

PICO Question 2: In patients with MCAO, does airway stenting impact mortality, compared to no stenting?
Recommendations:
- **In patients with MCAO, airway stenting can lead to improvement in survival and therefore, we suggest that it be pursued in the presence of attributable symptoms (Grade 2C)**

Remark: *There is no difference in outcomes between covered metallic and silicone stents.*

PICO Question 3: In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, does airway stenting impact liberation from mechanical ventilatory support?
Recommendations:
- **In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, we recommend airway stenting be considered, as it may lead to early liberation from ventilatory support (Grade 1C)**

Remark: *Early intervention should be considered in patients with MCAO that causes respiratory failure requiring mechanical ventilation.*

PICO Question 4: In patients with MCAO requiring airway stenting, do pulmonary hygiene measures reduce the incidence of stent-related complications, compared to no intervention?
Recommendations:
- **In patients with MCAO requiring airway stenting, we suggest that pulmonary hygiene measures be implemented to reduce the incidence of stent-related complications (Expert Consensus)**

Remark: *Studies are needed to assess the optimal regimen and efficacy of pulmonary hygiene measures.*

PICO Question 5: In patients with MCAO requiring airway stenting, do routine surveillance bronchoscopies reduce the incidence of stent-related complications, compared to only symptom-driven bronchoscopies?
Recommendation:
- **In patients with MCAO requiring airway stenting, we suggest that surveillance bronchoscopies after stenting be performed to detect stent-related complications in asymptomatic patients (Grade 2C)**

Remark: *Studies are needed to determine the ideal time for surveillance bronchoscopies. In the absence of quality evidence, we suggest that the first surveillance bronchoscopy be performed 4–6 weeks after stenting.*

PICO Question 6: In patients with MCAO requiring airway stenting, does silicone stenting reduce the incidence of stent-related complications, compared to hybrid metallic stenting (fully or partially covered)?
Recommendations:
- **In patients with MCAO requiring airway stenting, we suggest that either silicone or hybrid metallic stents be used (Grade 2B)**

Remark: *The choice of airway stent should be based on local availability, expertise, patient and airway-related factors.*

Small, retrospective studies including fewer than 100 patients have reported an improvement in Eastern Cooperative Oncology Group (ECOG) performance score (by at least 1; from ~3–4 to 2),[22–25] Modified Medical Research Council (mMRC) dyspnoea scale (by at least 1 grade; in 97%),[13,14,24,26,27] oxygenation,[28–31] forced expiratory volume (FEV_1), peak expiratory flow (PEF),[19,25,32–36] or 6MWD.[33]

Most studies utilized an endoscopy or operating room to perform the stenting procedure. Sicker patients and those requiring more complicated procedures may be better served by procedures under general anaesthesia in a dedicated procedure or operating room.[37] Similar benefits have been reported with both silicone and metallic stents based on inter-study comparisons.[13,22,23,26,38]

Rationale for Recommendations

MCAO can cause symptoms ranging from dyspnoea with exertion to shortness of breath at rest, cough, haemoptysis and difficulty clearing secretions which may lead to post-obstructive and recurrent infections. Even though the overall quality of evidence is low, there are a large number of small reports which demonstrate symptom improvement in the vast majority of patients who undergo airway stenting.[13–20] It is important, however, to carefully select patients who may benefit from the intervention (i.e., those who have symptoms attributable to the MCAO). In addition, procedural and clinical success are not the same[2]; opening an airway leading to little viable or poorly perfused parenchyma is likely to lead to no improvements in quality of life or performance status. The choice of airway stenting depends upon numerous institution, patient and provider-centric factors and practices vary.[8] There is no evidence that either quality of life or performance status will improve more with one stent type compared to another; however, no studies were specifically designed to evaluate for a difference between the two.

PICO Question 2

In patients with MCAO, does airway stenting impact mortality, compared to no stenting?

Recommendation

In patients with MCAO, airway stenting can lead to improvement in survival and therefore, we suggest that it

be pursued in the presence of attributable symptoms (Grade 2C).

Remark

There is no difference in outcomes between covered metallic and silicone stents.

Literature Review

No prospective study has directly compared the impact of airway stenting on survival versus no intervention. Given the acuity of presentation of patients with MCAO that may benefit from airway stenting, ethical and recruitment challenges may limit the feasibility of such trials in the future as well. Approximately 13% of patients with lung cancer have CAO,[1] which is associated with a higher hazard ratio (1.78) of death. Median survival in patients with MCAO is higher when the intervention (not limited to stenting) is successful.[39] Survival curves for those who have MCAO that has been successfully intervened upon match those without MCAO.[4] The only published randomized, controlled trial ($N = 78$) of silicone stenting versus no stent was terminated before their target enrollment (170 patients in each arm) and did not demonstrate any survival difference.[21] Published data on outcomes of stenting in treatment naïve versus previously treated patients is limited and to date, no study has addressed this question in a comparative prospective study. A subgroup analysis of the SPOC trial, however, showed that in pure endoluminal MCAO, when compared to no stenting, silicone stenting showed a beneficial effect on local recurrence in patients on second or more lines of treatment but not in those recommended for the first line of therapy.[21] Patients with MCAO who require airway stenting represent a critically ill cohort with a survival likely in the order of months (even with an intervention). In a prospective, multicentre registry, 22% (72 of 326) of patients with stents died within 30 days of the procedure compared to 9.7% (46 of 474) of patients with no stents ($p < 0.001$)[2]; patients with Y stents had higher mortality (OR 4.92 for Y stent vs. 1.72 for straight stent). This likely reflects how critical these patients are rather than an untoward complication of airway stenting, although causation cannot be excluded. A successful bronchoscopic intervention can be a good temporizing measure to allow patients to be able to receive cancer-directed treatment, which has been shown to be a predictor for better survival.[38,40–43]

A recent retrospective study of 106 patients comparing survival after airway stenting reported a slightly better survival in the silicone stent group compared to the metallic stent group (5.6 vs. 3.2 months).[44] Similar findings were noted in a 78 patients study comparing Y stents made of silicone or metal (Micro-Tech) (median survival 171 vs. 104 days).[45] These studies, beyond their design, are limited by not controlling for cancer-type, which is likely one of the most important predictors of long-term patient outcomes. Other studies, however, do not report differences in survival in patients receiving either silicone or metal stents,[46] and inter-study comparisons do not suggest any survival difference based on the stent type.[13,24,40,42,47–53]

Rationale for Recommendations

Patient survival is dependent on numerous factors including their comorbidities, performance status and cancer type and treatment. The dearth of prospective data to control for these factors makes it hard to demonstrate a direct impact of airway stenting on survival. Extrapolating from retrospective data and our clinical practice, it does seem that the airway intervention impacts survival as many of these patients would not be able to leave the hospital without restoration of airway patency. Successful airway stenting, by improving patient performance status, may allow patients to receive systemic therapy. It is hard to determine how much of the survival benefit could be directly from the airway stenting as opposed to the subsequent antineoplastic therapy that the patient receives. With improving systemic and targeted therapies, it will become even more important to bring the patients to a performance level that makes them eligible to receive these directed treatments. The current limited evidence largely suggests no difference between metallic and silicone stents in regards to survival, but this question has not yet been addressed in prospective comparative trials. The impact of airway stenting on liberating patients from invasive mechanical ventilation, in patients with respiratory failure from MCAO, is discussed separately under PICO 3.

PICO Question 3

In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, does airway stenting impact liberation from mechanical ventilatory support?

Recommendation

In patients with respiratory failure requiring invasive mechanical ventilation due to MCAO, we recommend airway stenting be considered, as it may lead to early liberation from ventilatory support (Grade 1C).

Remark

Early intervention should be considered in patients with MCAO that causes respiratory failure requiring mechanical ventilation.

Literature Review

The largest study reporting on the success of airway stenting to liberate patients in respiratory failure from invasive mechanical ventilation included 30 patients[41]; in this study, 93% (28 of 30) of patients were liberated from mechanical ventilation at 48 h. Other smaller studies,

predominantly reported as sub-group analyses, report success rates ranging from 50% to 100%,[26,30,47,54–59] with majority being liberated within 24 h of the intervention. Median reported survival in these studies ranged from 30 to 300 days and was better in those in whom the intervention was successful.[41,54,55]

Rationale for Recommendations

In patients in respiratory failure from MCAO requiring invasive mechanical ventilation, the small body of published data demonstrates that airway stenting is an effective intervention to liberate patients from the mechanical ventilator. The results can be seen quickly after the intervention, with the majority of patients being liberated within 24–48 h. It is not unreasonable to extrapolate this success to patients requiring non-invasive ventilatory support for their MCAO-attributable respiratory failure.[26] MCAO-related respiratory failure requiring invasive mechanical ventilation must be approached as a medical emergency warranting consideration for an intervention, if within the patient's pre-defined goals of care. The high success rate of airway stenting in these patients, however, may not be applicable to those presenting with a more chronic course to their respiratory failure, or those requiring prolonged periods of mechanical ventilation prior to airway stenting.

Despite the reported success, overall survival in these patients continues to remain poor, although in small series, it was several months. With improving systemic chemo, immuno- and targeted therapies, it remains to be seen whether survival will be significantly prolonged in this specific cohort of patients. However, weaning off mechanical ventilation is the first step to bridge patients to cancer-directed therapies or for palliative services for end-of-life care.

PICO Question 4

In patients with MCAO requiring airway stenting, do pulmonary hygiene measures reduce the incidence of stent-related complications, compared to no intervention?

Recommendation

In patients with MCAO requiring airway stenting, we suggest that pulmonary hygiene measures be implemented to reduce the incidence of stent-related complications (Expert Consensus).

Remark

Studies are needed to assess the optimal regimen and efficacy of pulmonary hygiene measures.

Literature Review

There are no studies directly evaluating the impact of pulmonary hygiene measures on reducing airway stent-related complications. Only one study[60] explicitly reported the regimen used (i.e., normal saline nebulization) after airway stenting. However, given the lack of a control arm, firm conclusions cannot be drawn.

Rationale for Recommendations

Most experts on this panel use saline nebulization as their pulmonary hygiene intervention. Whether normal (0.9%) saline or other more concentrated forms of saline (3% or 7%) are better remains to be determined. Based on anecdotal evidence of higher rates of biofilm and mucus plugging in patients with airway stents who are not compliant with their pulmonary hygiene measures, and given that these carry a very low adverse effect profile, we suggest their use in every patient who undergoes airway stenting for MCAO. In practice, bronchoscopists use a variety of other measures including expectorants (guaifenesin), mechanical techniques (flutter valve) and mucolytics (*N*-acetyl cysteine—inhaled or oral). There is no published evidence pertaining to efficacy of each of these techniques and formulations, alone or in combination in patients with airway stents.

PICO Question 5

In patients with MCAO requiring airway stenting, do routine surveillance bronchoscopies reduce the incidence of stent-related complications, compared to only symptom-driven bronchoscopies?

Recommendation

In patients with MCAO requiring airway stenting, we suggest that surveillance bronchoscopies after stenting be performed to detect stent-related complications in asymptomatic patients (Grade 2C).

Remark

Studies are needed to determine the ideal time for surveillance bronchoscopies. In the absence of quality evidence, we suggest that the first surveillance bronchoscopy be performed 4–6 weeks after stenting.

Literature Review

The largest study assessing the impact of surveillance bronchoscopies at 4–6 weeks included 134 patients (147 stents).[61] Sixty percent of asymptomatic patients were found to have at least one stent-related complication on follow-up bronchoscopy, although, the reported stent-related complications did not correlate with respiratory symptoms. Another study of 88 patients (47 with cancers; 101 stents) reported a sub-group analysis comparing surveillance bronchoscopy at 2–3 months to 'emergency' bronchoscopy prompted by respiratory symptoms.[62] Stent-

related complications were noted in 84% (26 of 31) of patients undergoing emergency bronchoscopy and 29% (9 of 31) of asymptomatic patients undergoing surveillance bronchoscopy. Only four asymptomatic-surveillance bronchoscopy patients required a therapeutic intervention. Other studies have used more intense surveillance bronchoscopy regimens[63,64]; however, in the absence of a comparison (no-surveillance) group, little can be inferred from the reported complication rates.

Rationale for Recommendations

The goal of surveillance bronchoscopies in asymptomatic patients with airway stents is to detect complications such as granulation tissue formation, earlier, at a time when it may be easier to intervene. A disadvantage of reactive interventions (i.e., after patients become symptomatic) is that immediate bronchoscopy for symptom palliation may not be feasible, and many patients may present acutely, occasionally in respiratory distress, requiring hospitalization (e.g., with a mucus plug or migrated stent). Limited published evidence favours the performance of surveillance bronchoscopies. Studies are needed to determine the true benefit of routine surveillance over symptom-driven bronchoscopies, and to determine the optimal time of the initial surveillance. The frequency of surveillance bronchoscopies after the initial surveillance is not standardized and is determined on a case-by-case basis. Institutional practices may vary based on ease of access to bronchoscopy and associated costs. Chest computerized tomography (CT) may detect some airway stent related complications and serve as an alternative to surveillance bronchoscopy. However, the performance of chest CT for surveillance is limited by what seems to be a lower sensitivity and specificity to detect endobronchial pathologies[65]; under-recognition (e.g., of granulation tissue) or overcalls (e.g., of mucus as endobronchial tumour or granulation) may limit its routine application as a surveillance tool. At the very least, outpatient follow-up to interview and examine the patients, with or without in-office spirometry, should be pursued to determine the need for a bronchoscopy.

PICO Question 6

In patients with MCAO requiring airway stenting, does silicone stenting reduce the incidence of stent-related complications, compared to hybrid metallic stenting (fully or partially covered)?

Recommendation

In patients with MCAO requiring airway stenting, we suggest that either silicone or hybrid metallic stents be used (Grade 2B).

Remark

The choice of airway stent should be based on local availability, expertise, patient and airway-related factors.

Literature Review

Common stent related complications include mucus plugging, granulation tissue and migration. Few studies report sub-group analyses of direct comparisons between silicone and metallic stents.[13,44–46,60] In these studies, there is no difference in reported complications based on stent type. Reported incidence of granulation tissue, mucus plugging and migration for straight silicone and metallic stents are 4%–51%, 9%–22% and 7%–17%,[3,13,35,36,44,52,60,66,67] and 2%–41%, 10%–23% and 1%–15%,[14,16,24,27,28,34,44,51,53,55,56,60,63,64,68–71] respectively. Reported incidence of granulation tissue, mucus plugging and migration for Y shaped silicone and metallic stents are 9%–33%, 5%–27% and 2%,[17,18,32,45,46,72] and 60%–70%, 5%–35% and 3%,[45,46,73–75] respectively. The large variation in incidence of granulation tissue and mucus plugging could be in part related to definitions used for reporting and biases inherent to the retrospective nature of the studies. In addition, the differentiation between granulation and tumour ingrowth is sometimes difficult in the absence of biopsy proven data. Metallic airways stent are prone to tumour ingrowth (usually through uncovered ends) or fractures, due to stent fatigue.[14,16,26,27,71,76,77] Mucus plugging and/or biofilm formation may lead to downstream parenchymal infections in 5%–40% of patients.[28,40,63,77,78] In a multicentre, registry study including 172 patients (195 stents), the median time to infection was 1 month (0–35).[77] Fully covered metallic stents (Merit Aero® stents) were reported to have increased risk of infection (HR = 1.98), while Dumon silicone tube stents had increased risk of migration (HR = 3.52). Silicone stents (HR = 3.32) and lower-respiratory tract infections (HR = 5.69) increased the risk of granulation tissue, and infections were associated with decreased survival (HR = 1.57). Procedure or complication-related deaths are rare.[28,68] There are no data to suggest different mortality rates between silicone and metallic stents, when used for MCAO.

Rationale for Recommendations

There is no conclusive evidence that the type of stent affects stent-related complications. Y stents, do however, expectedly migrate less often but may be associated with more mucus plugging. From the published data, is difficult to draw firm conclusions regarding stent-related complications, which in practice, are influenced by other provider (experience, stent choice/availability and sizing) and patient (cough-strength and CAO morphology)-related factors.

CONCLUSIONS AND FUTURE DIRECTIONS

This document intends to offer guidance regarding airway stenting in patients with symptomatic MCAO (Table 3). The strengths of this paper are its methodology, comprehensive literature review of all evidence on this topic and that it

includes the opinions and perspectives of experts in the field from 17 institutions across 11 countries. The limitations of this work arise from the poor quality of existing evidence. Therefore, our recommendations are either supported by evidence of low-quality or based on expert consensus. There is only one randomized, controlled trial that assessed the benefits of airway stenting; however, this study could not recruit to the targeted enrollment.[21] Ethical considerations, acuity of patient presentation, variability in type, location, extent and severity of MCAO, confounding comorbidities and treatments, as well as ensuring a suitable control group, are just a few of the challenges that researchers have to face when recruiting patients for studies of airway stenting in MCAO.

We expect better longer-term survival in patients with cancers obstructing the central airways due to improving anti-neoplastic therapies. Therefore, in future prospective studies, ability to undergo further anti-neoplastic therapy and ability and ease of subsequent stent removal should be incorporated as an individual or composite endpoint to accurately determine the overall impact of airway stenting in MCAO as part of multi-modal treatment strategies. Additional external beam radiation therapy after airway stenting may improve patient outcomes and survival.[38,43,79] However, given the dearth of evidence, this strategy is not standard of practice.

Stent design improvements may lead to lower complication rates. CT and intraprocedural airway measurements suffice for airway stent selection in the vast majority of CAO scenarios. Rarely, morphologically complex stenoses, may benefit from patient-specific three-dimensional (3D) stents. 3D printed stents using the patient's CT scan or an airway model have been recently used particularly for benign stenoses,[80–83] with only a few case reports of use in MCAO.[81,84] With advances in technology (including standardization of material and manufacturing), particularly with the availability of on-site 3D printing, in the future, these stents may be used more commonly for complex-morphology MCAO. For a transient stenosis, such as MCAO from a potentially rapidly treatable tumour, biodegradable stents are theoretically appealing. However, the properties (including time to degradation) and complications with these stents must be studied before they are considered for routine use. In a case series of six post-lung transplantation airway stenoses treated with biodegradable stents, four needed further stenting.[85] Drug-eluting stents, in principle, may reduce tumour-ingrowth, granulation tissue formation or biofilm formation; however, in-human testing remains to be conducted.[86,87]

Future studies must strive to demonstrate improvements in patient-centred outcomes, focusing on clinical rather than technical success. In multicentre studies, bronchoscopists should also aim to address comparisons between stent types and pulmonary hygiene measures. Studies should also investigate surveillance protocols including the timing, frequency and impact of follow up clinic visits, imaging (i.e., chest CT) and bronchoscopy in patients who have undergone airway stenting. We anticipate that as further evidence is generated in the current anticancer era, there will be a need to reassess stenting practices periodically, building on the recommendations presented in this manuscript.

CONFLICT OF INTEREST STATEMENT

H.D. serves as a consultant for Novatech. M.O. has received speaker fees from Olympus. S.M. serves as an educational consultant for Olympus, Johnson & Johnson, Boston Scientific. The other authors have nothing to disclose.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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