



Long-term efficacy and safety of the Dumon stent for benign tracheal stenosis: a meta-analysis

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Background: The short-term efficacy of Dumon stent has been well demonstrated. Across years, however, due to insufficient sample size and absent of the randomized controlled trial, no reliable conclusion could be reached for Dumon stent's long-term efficacy. So, we conducted the first meta-analysis to evaluate the long-term efficacy and safety of the Dumon stent for benign tracheal stenosis.

Methods: Data on related trials were obtained by doing a literature search in PubMed, Web of Science and Cochrane Library. Random-effect and fixed-effect models were used to calculate the efficacy and incidence of complication of Dumon stent placement.

Results: A total of 395 patients from 8 studies were included in this study, revealing that the stability rate was 41.12% (95% CI, 34.85–48.52%) of Dumon stenting. Further, a curative rate of 40.74% (95% CI, 34.92–47.53%), and efficacy of 75.49% (95% CI, 70.89–80.39%) were obtained from this study. Analysis of the incidence of complications indicated 25.04% of migration (95% CI, 17.52–35.79%), 15.66% granulation (95% CI, 9.39–26.11%) and 23.82% of mucus retention 23.82% (95% CI, 13.77–41.20%).

Conclusions: Dumon stent has a moderate efficacy for treating benign tracheal stenosis with approximately 20% incidence of complication, regular bronchoscopy follow-up should be conducted. Thus, further research is required to modified Dumon stenting.

Keywords: Silicone stent; bronchoscopy; tracheal stenosis; meta-analysis

Submitted Jun 29, 2020. Accepted for publication Nov 05, 2020.

doi: 10.21037/jtd-20-2327

View this article at: <http://dx.doi.org/10.21037/jtd-20-2327>

Introduction

Benign tracheobronchial stenosis which refers to abnormal narrowing of trachea and bronchus, is commonly caused by tracheal intubation, prior tracheotomy, tuberculosis, granulomatosis with polyangiitis and idiopathic strictures. Symptoms of tracheobronchial stenosis could develop immediately after extubation or progress slowly over 50% airway obstruction occurs. The main symptoms of tracheal

stenosis include stridor, dyspnea, and wheezing. Notably, some patients may present with lung function decline even though the respiratory symptoms absent (1).

Currently, surgery (tracheal resection and end-to-end anastomosis) serve as the most effective treatment for benign tracheal stenosis. A previous study reported over 90% success rate of surgery for treating airway stenosis, with only 10% complications occurred (2). However, less than 10% patients with tracheal stenosis are operable and

resectable (3), since the surgery treatment has been limited by the high risks associated with anaesthesia and surgery, the length of the tracheal resection and the extent of the lesion. In addition, surgery-related deaths could increase thirteen-fold for patients with risk factors for anastomotic complications (diabetes, long-segment stenosis, previous tracheal surgery, etc.) (4). Thus, timely interventional bronchoscopy might contribute to the preferred approach for patients with inoperable stenosis, hypoxemia or related-respiratory failure (5).

Interventional bronchoscopy, present fewer complications compared with surgery, are more conducive to treat with elderly or patients with severe tracheal stenosis. Interventional managements include balloon dilatation, laser-assisted ablation, cryotherapy, and placement of stents, all of which could be applied alone or in combination (6). However, bronchoscopy has been reportedly induced airway injury, related granulation tissue and fibrous scar after interventional treatment (7).

Airway stenting is commonly used for maintaining luminal patency and providing structural support. Currently, the use of metallic stents in benign airway stenosis is controversial for its long-term severe complications. Furthermore, it has been a challenge to remove the prolonged placed metal stents from the airway, thus, FDA warned against the use of metallic stents for treating benign airway obstruction (8). Silicone stents, characterized by superior tolerance and less complications, display a good efficacy in patients with benign airway narrowing. Dumon silicone stent which was invented by JF Dumon in the 1980s, has a hollow and cylindrical shape, with external studs to prevent migration. Dumon stent is the most widely used silicone stent and considered as 'gold standard' for inoperable benign tracheal stenosis (9).

A previous study reported over 90% of patients who underwent silicone stent placement had rapid alleviation from dyspnea (10). However, assessing the long-term efficacy of silicone stent, includes stability rate, curative rates and incidence of restenosis might conducive to assess whether silicone stents could be used for treating benign tracheal stenosis. Whereas, the randomized controlled trials, prospective or retrospective studies on silicone stents with large sample sizes are currently absent. Here, we conducted a meta-analysis of retrospective studies to explore the long-term efficacy and safety of the Dumon stent as a treatment option for benign tracheal stenosis. We present the following article in accordance with the PRISMA reporting checklist (available at <http://dx.doi.org/10.21037/jtd-20-2327>).

Methods

Cochrane Handbook (11) and the PRISMA guidelines were used to guide the designing this study (12).

Inclusion criteria

Studies that satisfied the following criteria were included in this meta-analysis; (I) studies that included patients diagnosed with benign airway stenosis using bronchoscopy; (II) studies that included patients underwent silicone stent replacement; (III) studies where Dumon silicone stents were used; (IV) studies that included data on stent removal, stent stability, restenosis, or complications related to stent placement.

Exclusion criteria

Studies that only included malignant airway stenosis or those included cases with benign and malignant stenosis were excluded. Furthermore, we excluded the studies that investigated the effects of metallic stents. In addition, case reports and review articles were excluded. Articles written in non-English languages were not included in this study.

Search strategy

We conducted a literature search on Cochrane Library, PubMed (from 1981 to October 2018), the Web of Science (from 1981 to October 2018), and Google Scholar databases. The search algorithm was set as follows: ((benign AND ("tracheal stenosis"[MeSH Terms] OR ("tracheal" AND "stenosis") OR "tracheal stenosis")) OR (airway AND ("constriction, pathologic"[MeSH Terms] OR ("constriction" AND "pathologic") OR "pathologic constriction" OR "stenosis"))) AND ((Dumon AND ("stents"[MeSH Terms] OR "stents" OR "stent")) OR (("silicones"[MeSH Terms] OR "silicones" OR "silicone") AND ("stents"[MeSH Terms] OR "stents" OR "stent")))).

Data retrieval

All data were independently retrieved by two investigators (DC and YC). Disagreements were resolved by discussions between the two reviewers and an independent expert. Although some studies did not contain all required information, the following information were extracted from each study: first author, year of publication, number

of patients, mean duration of stent placement, pathogeny of stenosis, treatment events including stent removal, stent stability, restenosis, and complications.

Quality assessment

The risk of bias was assessed by using the Newcastle-Ottawa scale (13). The overall score for each article was set at 9:4 for selection, 2 for comparability, and 3 for outcomes. Final score of 1–3, 4–6 and over 7–9, were defined as of low, moderate, and high quality respectively.

Data synthesis

All included studies were placed into three subgroups: <6, 6–12, and >12 months groups based on the mean duration of Dumon stenting. These subgroups were used to assess the relationship between duration of stent application and efficacy. Further, we divided the study population into two groups, the palliative group and the treatment group, according to the aims of stent placement. The treatment group was used to study the long-term efficacy, while all the study population was used for analyzing the incidence of complications. Four indexes were chosen to evaluate the efficacy of Dumon stent for benign tracheal stenosis; (I) the curative rates (defined as the number of patients who had their stents successfully removed without symptomatic restenosis in 1 year); (II) the stability rates (defined as the number of patients who maintained stable stent placement); (III) the effective rates (defined as the sum of curative and stability rates added together) and (IV) the restenosis rates.

Statistical analysis

The total percentage for each event and number of cases in each study were obtained. The pooled effect sizes (ES), which denoted median “rates” were calculated and 95% confidence intervals (95% CI), were used. Cochran’s χ^2 test and I^2 were used to evaluate the heterogeneity of effect estimates; $P < 0.05$ or $I^2 > 50\%$ was considered statistically significant. A fixed-effects model was used except for cases had no significant heterogeneity. Studies with zero events were handled as described by Bradburn *et al.* (14) Publication bias was evaluated using the Egger linear test and a funnel plot was generated. All statistical analyses were conducted with R version 3.5.1.

Results

Study characteristics

We identified a total of 253 records from literature. Two hundred and twenty-nine out of 253 studies were excluded according to the inclusion and exclusion criteria. After reviewing the full text of the remaining 24 studies, 16 were excluded (*Figure 1*). A total of 8 retrospective studies comprising 395 patients met the inclusion criteria of this study (7,15–21). The characteristics of included studies were shown in *Table 1*. The sample sizes of the 8 studies ranged from 13 to 125. Most of the patients in these studies were young or middle-aged (mean age was 29–59 years). All studies focused on the treatment of benign airway stenosis patients using Dumon stent. Additionally, all 8 articles were single-arm studies, as shown by analysis using the Newcastle-Ottawa scale. Furthermore, 2 studies were of low quality while the remaining 6 were of moderate quality.

Efficacy of Dumon stenting

Analysis using the fixed effects models showed 40.74% curative rates ($I^2=40.1\%$, $P=0.12$, 95% CI, 34.92–47.53%), and the fixed effects model calculations showed 41.12% stability rate of Dumon stent in benign airway stenosis ($I^2=37.9\%$, $P=0.14$, 95% CI, 34.85–48.52%). In addition, effective rate of the stent approach as calculated by fixed effects model was 75.49% ($I^2=37.9\%$, $P=0.11$, 95% CI, 70.89–80.39%). The restenosis rate of 31.53% (95% CI, 26.79–37.14%) was obtained using the random effects model (*Figure 2*).

Safety of Dumon stenting

In this study, safety events considered in this study included stent migration, granulation, and mucus retention. The rates of stent migration, granulation, and mucus retention were calculated using the random effects model for high heterogeneity; The stent migration rate of 25.04% (95% CI, 17.52–35.79%), while 15.66% of granulation rate was (95% CI, 9.39–26.11%), and 23.82% mucus retention rate (95% CI, 13.77–41.20%) were obtained (*Figure 3*).

Subgroup analysis

Subgroup analysis for stent duration was conducted using efficacy indexes. However, significant differences

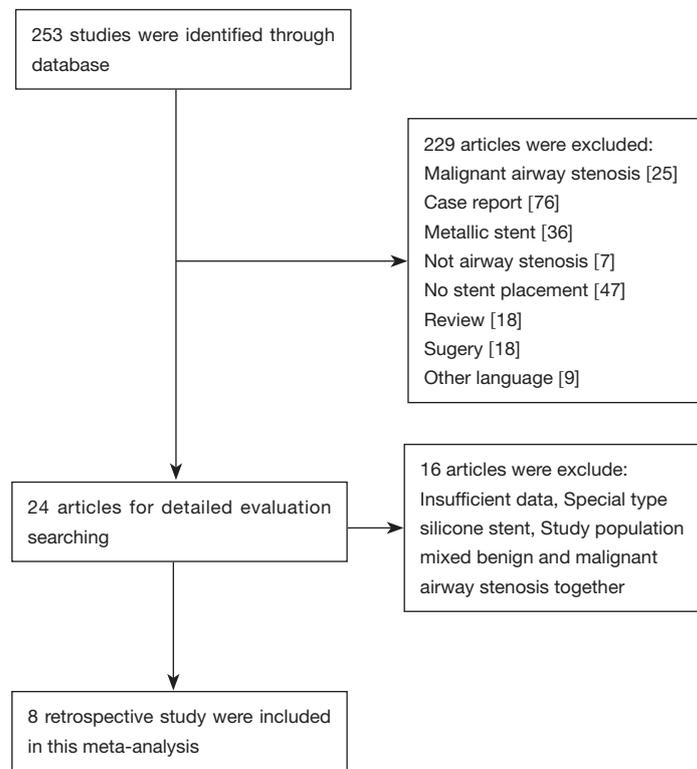


Figure 1 Flowchart demonstrating inclusion and exclusion criteria.

Table 1 Baseline characteristics of eight trials included for analysis

Author	Pathogeny of stenosis	Type of stent	Mean age	Cases	Treatment group	Mean duration of stent (months)	Quality
Martinez (1996)	Postoperative stenosis, postintubation stenosis	Dumon	52	63	48	12.1	Moderate
Vergnon (2000)	Postoperative stenosis, postintubation stenosis	Dumon	39.5	13	13	19.6	Low
Ryu (2006)	Tuberculosis, postintubation stenosis	Dumon	33	39	39	16	Moderate
Cavaliere (2007)	Postintubation stenosis	Dumon	50	48	47	11.6	Moderate
Gallucio (2009)	Postoperative stenosis, postintubation stenosis	Dumon	29	48	39	18	Moderate
Jeong (2012)	Postoperative stenosis	Dumon	59	19	19	7	Low
Dalar (2016)	Postoperative stenosis, postintubation stenosis	Dumon	52	125	111	11.9	Moderate
Karush (2017)	Postoperative stenosis, postintubation stenosis	Dumon	54	40	36	3.03	Moderate

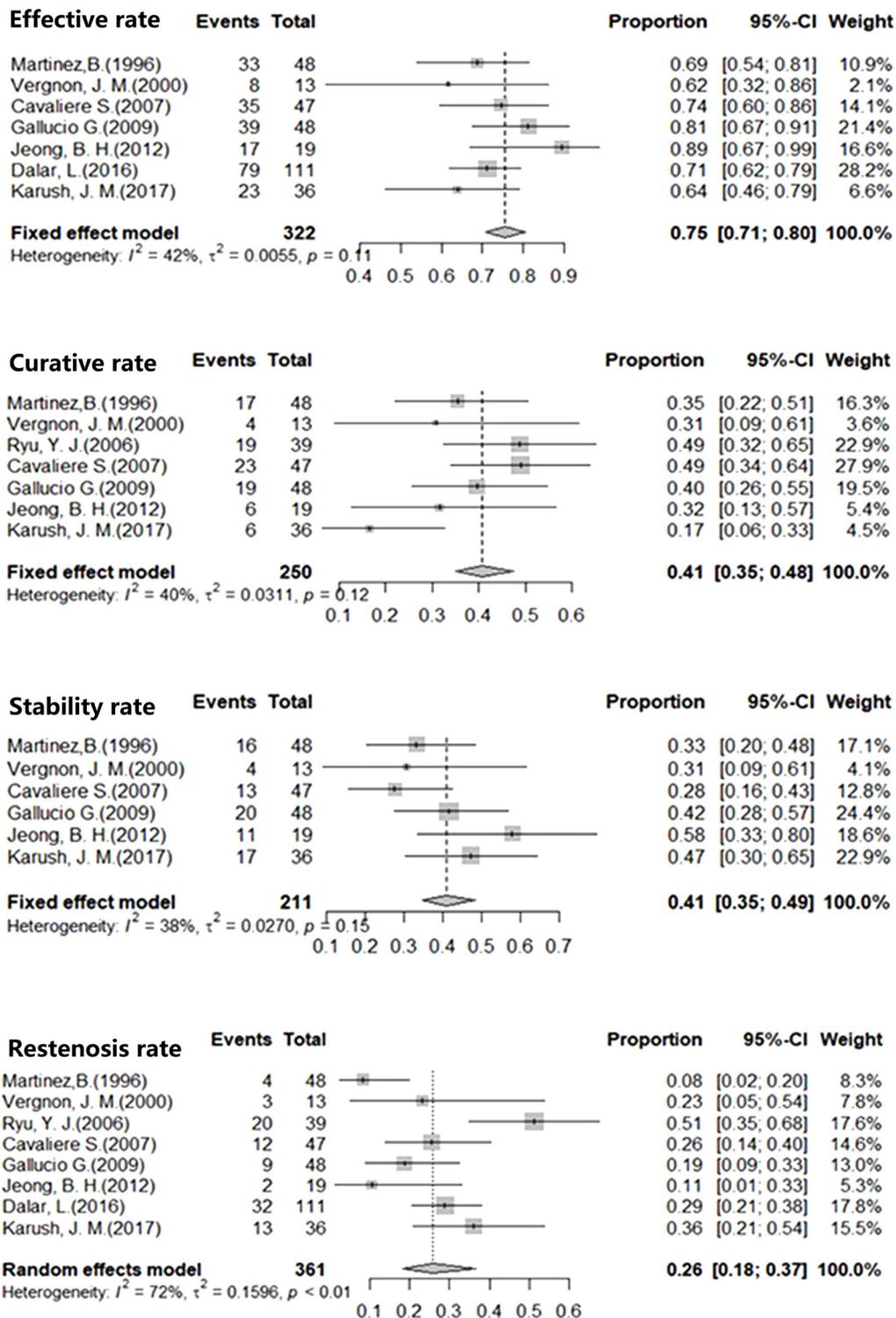


Figure 2 Forest plot for the meta-analysis of efficacy indexes. CI, confidence interval.

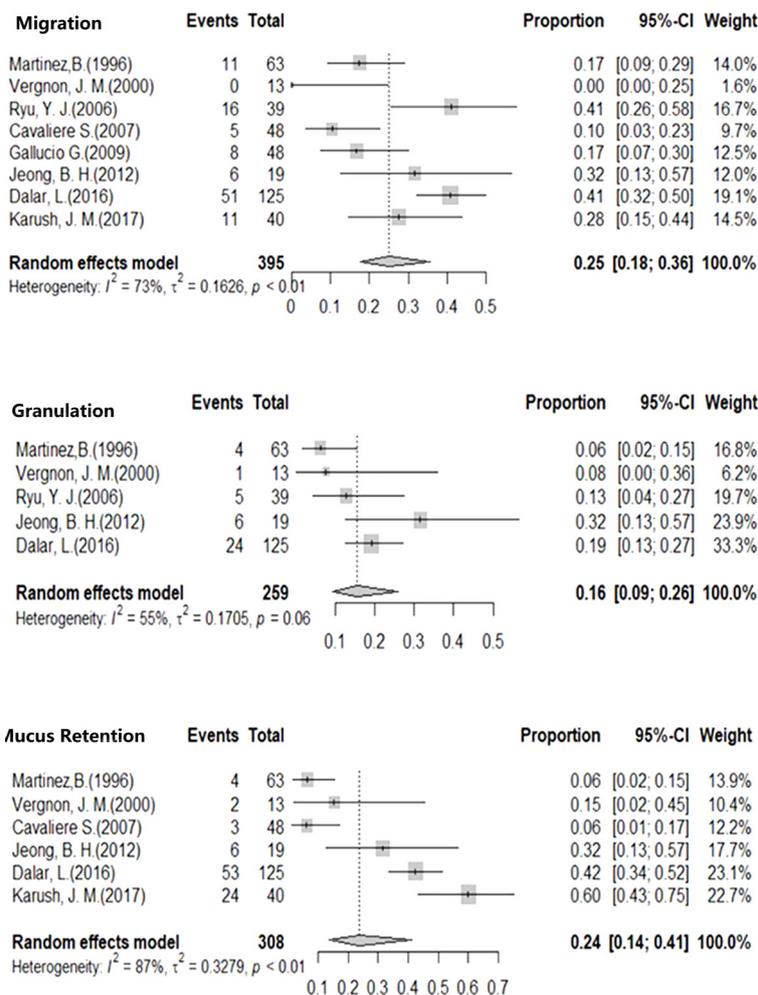


Figure 3 Forest plot for the meta-analysis of safety events. CI, confidence interval.

between subgroups were only observed for the removal group (P=0.0402). The curative rate in the <6-month group was 16.67% (95% CI, 8.03–34.60%), 43.66% in the 6–12-month group (95% CI, 29.95–63.64%), and 40.91% in the >12-month group (95% CI, 33.65–49.74%) (Figure 4). Post hoc test, showed significant differences between the <6-month group and the other two groups (P<0.05). There were no significant differences in efficacy rates between 6–12-month and >12-month groups (Figure S1).

Publication bias

A P value of 0.831 for the Egger linear test was obtained, therefore, no publication bias was not observed in this meta-analysis (t=0.22486). Consistent with the result of Egger linear test results, a symmetrical funnel plot was obtained (Figure 5).

Discussion

Dumon stent has been used for the treating airway stenosis for about 40 years. However, the efficacy and related complications of Dumon stent has not been well elucidated by prospective clinical trials multicenter study. To our knowledge, this is the first meta-analysis study to include retrospective, single-arm, and single-center studies on use of Dumon stent for treating benign tracheal stenosis. The current study showed Dumon stent has 75.49% effective rate and approximately 20% incidence of complications (migration, granulation, and mucus retention) indicating that Dumon stent had moderate efficacy and safety for airway stenosis.

Previous studies reported that over 90% of patients experienced quick relief of dyspnea (10), rather than the

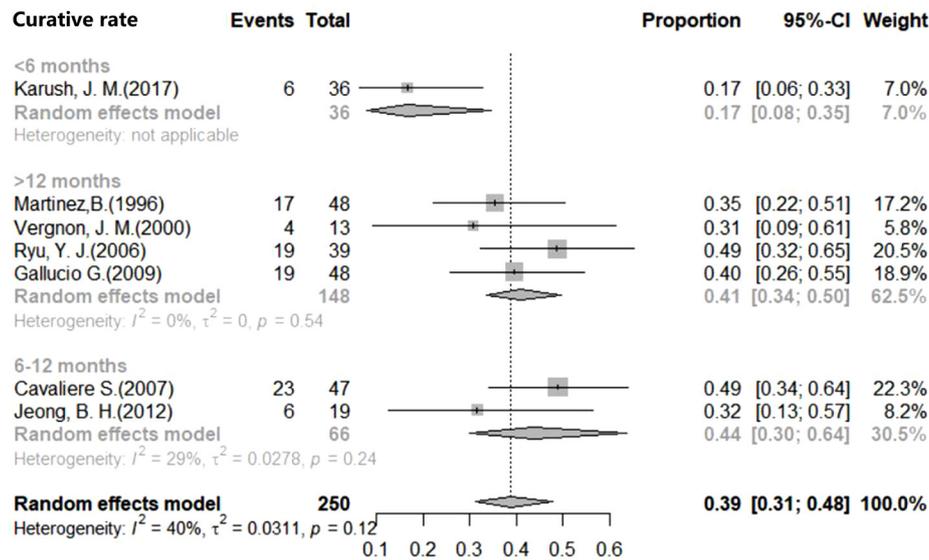


Figure 4 Forest plots for subgroup meta-analysis of curative rate based on median follow-up. CI, confidence interval.

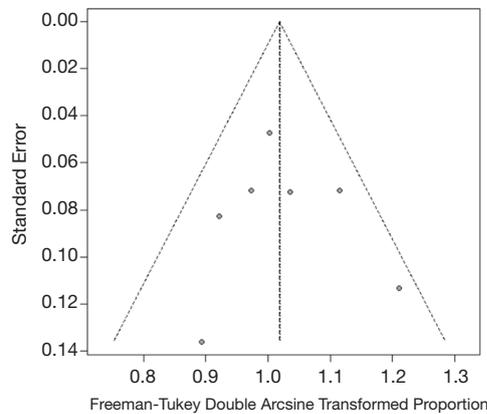


Figure 5 Funnel plot of studies included in this meta-analysis.

complete elimination of tracheal stenosis. In attempt to evaluate the placement of silicone stent, Borg scale, lung function, CT measurement of stenosis, curative rates (successful removal of the stent) and stability rates (stenosis remaining stable after stent implantation) after stent placement (8). Curative rates and stability rates are summed up to serve as a long-term index denoted as effective rate to evaluate the overall performance of Dumon stenting. In this study, we employed the restenosis rate as a part of efficacy rate to evaluate of the treatment failure. In the current analysis, the stability rate was 41.12% (95% CI, 34.85–48.52%), the curative rate 40.74% (95% CI, 34.92–47.53%), the effective rate 75.49% (95% CI,

70.89–80.39%) and the restenosis rate 31.53% (95% CI, 26.79–37.14%). These results indicated that Dumon stent was effective in over 75% patients with tracheal stenosis. However, more than 40% of patients had to maintain stent placement to ensure the airway luminal stability, and stent therapy is not effective in approximately 30% of patients.

Analysis of duration of stent placement showed no significant differences for effective rates, stability rates, and restenosis rates in all three subgroup. Moreover, the effective rates, stability rates and restenosis rates showed no correlation with the duration of stent use. However, the curative rates were significantly lower in <6-month group compared with those in 6–12-month and >12-month group. These findings implied that untimely early removal of stent should be avoided to ensure the stability of that stenosis lesion with stents. The appropriate timing of stent removal is not definite. Our results were compatible with those of Dumon’s report that stents should be left in place for more than 6 months (22), which could significantly improve the success rate of stent removal without increasing the restenosis rate. Verma *et al.* explored the definite stent removal time by using computerized tomography (CT) in post-tuberculosis tracheobronchial stenosis (23). In this study, the length of air pockets (tracheobronchial air columns in the space between the outer surface of the stent and the adjacent airway wall) in CT was used as an indicator for stent removal. Pockets longer than 1 or 2 cm could be used to indicate a successful stent removal, with 84%

sensitivity and 50% specificity.

The major complications of Dumon stent includes migration, granulation, and mucus retention (10,24). Meta-analysis showed various incidences of complications from those reported in the previous studies, migration rate at 18.6%, granulation rate at 17.2%, mucus retention rate at 5.7% (22). In our study, migration rate was slightly higher (25.04%) while the incidence of mucus retention was significantly higher (23.82%) than the incidence reported than those reported in previous study (9). Silicone stent related complications are commonly occurred in patients with benign tracheal stenosis. Severe mucus retention induces asphyxia and requires immediate clearance or respiratory interventions to prevent suffocation. Extensive migration of stent near the vocal cord could cause immediate asphyxia. External fixation of the silicone stent is used to reduce the occurrence of migration, whereas, the curative effect is commonly limited by the complex technique and procedure (25,26). The accurate assessment of stenosis lesion and precise measurement of lumen dimensions might be of great important to improve the efficacy of airway stenting. Regular bronchoscopy follow-up should be conducted after Dumon stenting for early identification and management of related complications.

This study had several limitations. Firstly, the definite timing for Dumon stent remove were absent. The current study indicated that Dumon stent should be implanted for at least 6 months before removal. Secondly, as the study population was small, the included patients could not grouped by etiology of benign tracheal stenosis. Shin *et al.* reported a clinical significant difference in efficacy between post-intubation tracheal stenosis (PITS) and post-tracheostomy tracheal stenosis (PTTS). Silicone stent removal was achieved in 46.2% of patients in the PITS group and in 33.0% of patients in the PTTS group ($P=0.063$) (27). Thirdly, we only studied Dumon stent which is the most common airway stent, rather than including the other types of silicone stents, such as natural, dynamic and polyflex. Moreover, the current study did not investigate the other non-surgical treatment (i.e., balloon-dilation or laser ablation) in pre-and postoperative care, which might affect the prognosis of stent treatment. Finally, this meta-analysis only included retrospective single-arm studies and we only included studies reported in English, it's worth noting that tuberculosis related airway stenosis, one of the most common type of benign tracheal stenosis, post-tuberculosis airway stenosis, is highly prevalent in Asia (28).

Recent studies have reported some novel designs of silicone stents. Oki *et al.* conducted a retrospective study on a novel silicone stent, designed to fit in the primary right carina for treating airway stenosis (29). Advances in Materialogy have increased interest in study of customized stents. Gildea *et al.* (30) reported the application of 3D patient-specific stent in the treatment of Wegener's granuloma. Drug-eluting stents have been designed for treating airway infections and granulation (31,32).

Conclusions

Dumon stent has a moderate efficacy for treating benign tracheal stenosis with approximately 20% incidence of complication, regular bronchoscopy follow-up should be conducted. Multi-center, prospective clinical trials should be highlighted and performed for overall assessment of the silicone stent. Furthermore, novel designs, customize stent and tissue-engineering stent would be a crucial and promising in the development of airway stenting.

Acknowledgments

To memorize the founder silicone stent, inventor of Dumon stent, JF Dumon (1939–2020), R.I.P.

Funding: None.

Footnote

Reporting Checklist: The authors have completed the PRISMA reporting checklist. Available at <http://dx.doi.org/10.21037/jtd-20-2327>

Peer Review File: Available at <http://dx.doi.org/10.21037/jtd-20-2327>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/jtd-20-2327>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Cite this article as: Chen DF, Chen Y, Zhong CH, Chen XB, Li SY. Long-term efficacy and safety of the Dumon stent for benign tracheal stenosis: a meta-analysis. *J Thorac Dis* 2021;13(1):82-91. doi: 10.21037/jtd-20-2327

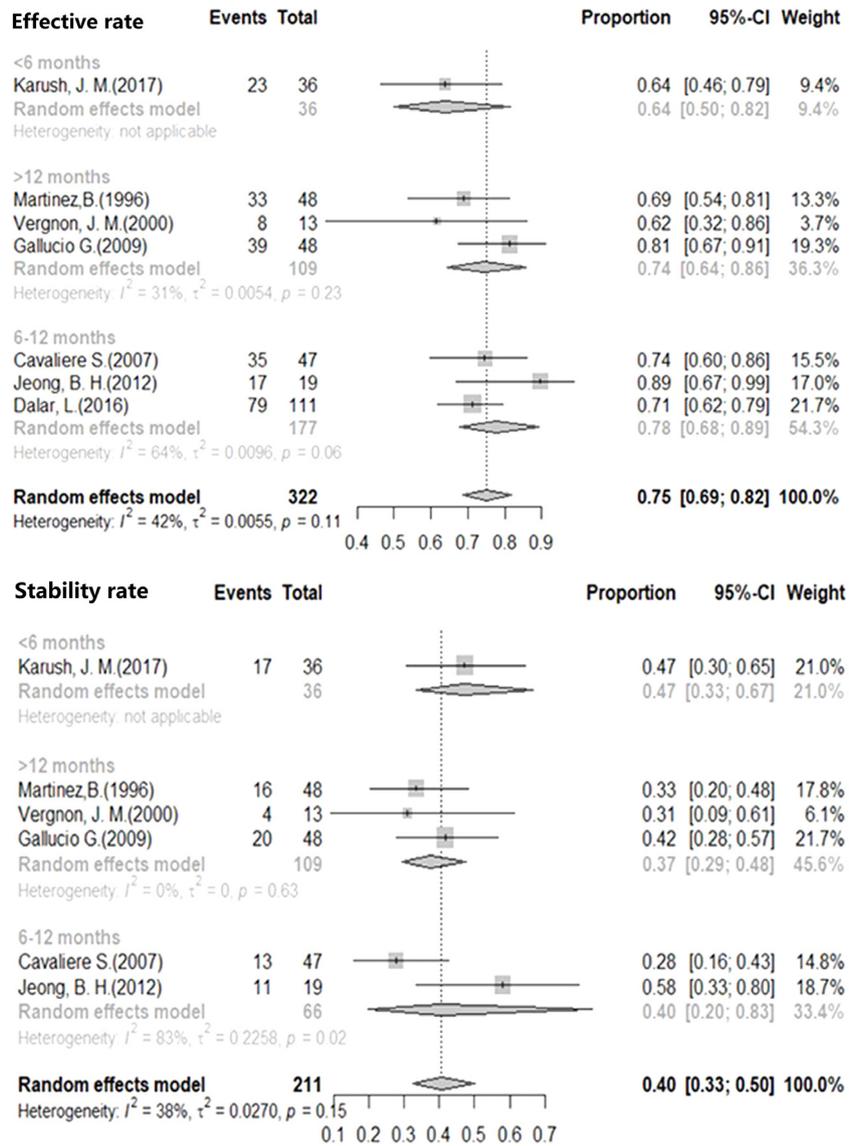


Figure S1 Forest plots for subgroup meta-analysis of effective rate and stability rate based on median follow-up. CI, confidence interval.