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**ORIGINAL ARTICLE**

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## **Clinical Outcomes of Carotid Angioplasty and Stenting for Radiation-associated Carotid Artery Stenosis**

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### **ABSTRACT**

**Objective:** To investigate the procedural complication rate, restenosis rate, and clinical outcomes after carotid angioplasty and stenting in patients with radiation-associated carotid stenosis.

**Methods:** All patients with a history of head and / or neck radiation referred to Queen Elizabeth Hospital, Hong Kong, for carotid angioplasty and stenting for carotid artery stenosis between January 2008 and December 2013 were identified. Their clinical information, and procedural and imaging findings were reviewed. All procedures were performed by a dedicated team of neurointerventionists. The mean degree of stenosis was 75.1% (range, 50.0%-94.1%). Standardised, regular postoperative follow-up with clinical and Doppler ultrasound assessments was scheduled for all patients.

**Results:** Forty-five carotid arteries in 40 patients with a history of head and neck irradiation were stented in this study. The mean age was 63.3 years; 36 (90.0%) patients had radiotherapy for nasopharyngeal carcinoma. The mean time interval between radiotherapy and carotid angioplasty and stenting was 228.8 months (range, 8-487 months). The mean degree of stenosis was 75.1%. Fourteen (31.1%) patients who underwent carotid angioplasty and stenting had contralateral carotid artery occlusion. Embolic protection devices were used in 37 (82.2%) procedures. There was one (2.2%) procedural complication, with dissection of the left common carotid artery during catheterization for left internal carotid artery stenting. The mean follow-up period was 29 months (range, 1-66 months). The ipsilateral stroke-free survival rates were 97.8% at 6 months, 95.1% at 1 year, and 84.0% at 5 years. The restenosis-free survival rates were 95.0% at 6 months, 92.5% at 1 year, and 74.0% at 5 years. No 30-day mortality was identified. Two subarachnoid haemorrhages and one transient ischaemic attack occurred in the 30-day postoperative period. On subsequent follow-up, four (10.3%) patients died at a mean interval of 19 months after the procedure.

**Conclusion:** We demonstrated that carotid angioplasty and stenting is safe in patients with radiation-associated carotid artery stenosis. The long-term clinical outcomes of ischaemic neurological event and restenosis were satisfactory.

**Key Words:** Angioplasty; Carotid stenosis; Radiotherapy; Stents

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## 中文摘要

### 頸動脈支架置入血管成形術治療放射相關性頸動脈狹窄的臨床效果

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**目的：**探討頸動脈支架置入血管成形術（CAS）治療放射相關性頸動脈狹窄的術中併發症發生率、術後再狹窄率和臨床效果。

**方法：**本研究的對象均於2008年1月至2013年12月期間有頭部和/或頸部放射史，並因頸動脈狹窄須接受CAS而被轉介至香港伊利沙伯醫院的患者。本文回顧了病人的臨床資料、手術和影像學發現。所有手術均由一個神經介入醫生專科組進行。頸內動脈平均狹窄度為75.1%（介乎50.0%-94.1%）。為所有患者安排了標準化的術後定期隨訪，包括臨床和超聲多普勒評估。

**結果：**為40名有頭部和/或頸部放射史的患者安裝了45條頸動脈內安裝了支架。患者平均年齡63.3歲；其中36人（90.0%）因鼻咽癌接受放射治療。放射治療與CAS的時間間隔為228.8個月（介乎8-487個月）。頸動脈平均狹窄度為75.1%。接受CAS的患者中，14人（31.1%）有對側頸內動脈阻塞。37例（82.2%）接受栓塞保護裝置。有1例（2.2%）出現術中併發症，於左頸內動脈支架置入術中插管時切開了左頸總動脈。平均隨訪時間為29個月（介乎1-66個月）。6個月、1年和5年的同側無中風生存率分別為97.8%、95.1%和84.0%。無再狹窄生存率分別為95.0%、92.5%和74.0%。30天死亡率為0%。術後30天內出現兩宗蛛網膜下腔出血和一宗短暫性腦缺血的病例。術後平均19個月內有4名患者（10.3%）死亡。

**結論：**本研究證明使用CAS治療放射相關性頸動脈狹窄是安全的。神經缺血性損傷和再狹窄治療的長期臨床結果令人滿意。

## INTRODUCTION

Cerebrovascular disease is a major cause of morbidity and mortality around the world.<sup>1,2</sup> In Hong Kong, cerebrovascular disease was the fourth leading cause of death and there were 26,487 related in-patient discharges in 2011.<sup>3</sup> Although the prevalence of extracranial carotid artery stenosis was shown to be much lower in the Asian population when compared with the Caucasians,<sup>4</sup> it remains an important and treatable cause of stroke.

Radiation has been shown to induce changes similar to atherosclerosis.<sup>5</sup> Patients who receive radiotherapy to the head and neck regions have a high risk of developing significant carotid artery stenosis.<sup>6</sup> Given the endemicity of nasopharyngeal carcinoma in the southern Chinese,<sup>7</sup> radiation-associated carotid artery stenosis is relatively common in Hong Kong. Due to the high risk of carotid endarterectomy in radiation-associated carotid stenosis,<sup>8</sup> transluminal angioplasty and stenting have become widely accepted treatment alternatives in this group of patients. However, there are only a few

studies on the clinical outcomes of carotid angioplasty and stenting (CAS) in radiation-associated stenosis. The objective of this retrospective study was to investigate the procedural complication rate, restenosis rate, and clinical outcomes after CAS in patients with radiation-associated carotid stenosis.

## METHODS

### Patient Population

All patients with a history of head and/or neck radiation referred to Queen Elizabeth Hospital, Hong Kong, for CAS for carotid artery stenosis between January 2008 and December 2013 were identified. Clinical information was assessed using electronic patient records (ePRs). Procedural and imaging findings were retrieved with both ePRs and Picture Archiving and Communication System. All preoperative clinical assessments were performed by either a neurosurgeon or a vascular surgeon experienced in endovascular interventions. Preoperative non-invasive imaging examinations included Doppler ultrasound in all patients, in combination with either computed

tomographic angiography or magnetic resonance angiography for anatomical assessments. Symptomatic carotid stenosis of >70% was referred for intervention. Stenosis of >50% was also treated if contralateral carotid artery was occluded. For asymptomatic carotid stenosis of >70%, CAS was mainly performed for pre-coronary artery bypass grafting preparations or patients with imaging-documented silent cerebral infarcts.

## Procedures

All procedures were performed by a dedicated team of neurointerventionists with at least one experienced operator who had performed more than 10 CAS procedures per year in the past 2 years. The procedures were undertaken in a biplanar neuroangiographic suite or an endovascular operating room. Diagnostic carotid angiograms were performed on ipsilateral carotid arteries to grade the internal carotid artery (ICA) or common carotid artery (CCA) stenosis according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria.<sup>9</sup> Transfemoral approaches under local anaesthesia were used for all CAS procedures. All CAS procedures were performed using the Carotid WALLSTENT Monorail Endoprosthesis system (Boston Scientific, Massachusetts, US). Embolic protection devices with FilterWire EZ (Boston Scientific, Massachusetts, US) were used at the discretion of the operators. Peri-procedural drug therapy included a combination of antiplatelet medications plus aspirin (80/160 mg daily started at least 5 days preoperatively and continued indefinitely after CAS), clopidogrel (75 mg daily started at least 5 days preoperatively and continued at least 3 months after CAS) and intra-operative heparinisation (with target activated clotting time of 250-300 s).

## Postoperative Follow-up

Neurological assessments were performed by neurosurgeons or vascular surgeons immediately after the procedure, at discharge, at 1 month after CAS, and thereafter at 3 to 6 months, at 12 months and once every year. Opportunistic assessments were performed when the patients attended clinics or were admitted to our hospital or other network hospitals in Hong Kong.

As per protocol, imaging follow-up using Doppler ultrasound was performed at post-procedural day 1, at 3 months, 6 months, 12 months, and then once every year, if the patient was asymptomatic. Ad-hoc Doppler ultrasound was performed when a neurological event developed. Doppler ultrasound criteria proposed by

Robbin et al<sup>10</sup> were used to screen for significant restenosis. Diagnostic carotid angiograms were subsequently performed to confirm significant (>70%) restenosis.

## Statistical Analysis

Event-free survival (defined as absence of ipsilateral ischaemic event and restenosis), ipsilateral ischaemic event-free survival, and restenosis-free survival were assessed for the 45 stented vessels. Ischaemic events included cerebral infarcts and transient ischaemic attacks. Restenosis was defined as a diameter reduction of >70% by NASCET criteria. Cumulative survival was calculated using Kaplan-Meier analysis. The Statistical Package for the Social Sciences (Windows version 16.0; SPSS Inc, Chicago [IL], US) was used to perform the statistical analysis.

## RESULTS

### Patient Characteristics

A total of 61 procedures were identified during the study period. Eleven CAS procedures for restenosis were excluded. Two were excluded due to insignificant irradiation to carotid arteries by radioactive iodine for hyperthyroidism. Three procedures were abandoned and excluded because CAS was regarded technically unfeasible as intra-procedural diagnostic carotid angiograms showed total occlusion of the target carotid arteries.

Forty-five carotid arteries in 40 patients (32 men and 8 women) were stented in this study. Five patients had bilateral stenosis which had been managed with interventional therapy: bilateral CAS had been performed in one single session in two patients and as two-staged procedures in three patients. The mean ( $\pm$  standard deviation) age was 63.3 ( $\pm$  8.3) years (range, 48-78 years). Of the 40 patients, 35 (87.5%) had at least one cardiovascular risk factor. Nasopharyngeal carcinoma was the most frequent head and neck cancer in this study group (n=36; 90.0%). The mean time interval between radiotherapy and CAS was 228.8  $\pm$  100.2 months (range, 8-487 months). Majority of CAS procedures (36/40, 90.0%) were performed for symptomatic stenosis. Patient demographic and characteristics are summarised in Table 1.

### Carotid Angioplasty and Stenting

Characteristics of the CAS procedures are summarised in Table 2. Contralateral carotid artery occlusions were noted during 14 (31.1%) CAS procedures. Embolic

protection devices were used in 37 (82.2%) procedures. One stent was deployed in 36 (80.0%) procedures. The stents were placed across carotid bifurcations in 33 (73.3%) procedures. Significant residual stenosis, defined as >20% by NASCET criteria, was found in four procedures, accounting for an overall technical success rate of 91.1%.

**Table 1.** Demographics of patient population included in the study.

Characteristics	Value*
Age (years)	63.3 ± 8.3 (48-78)
Sex	
Male	32 (80.0)
Female	8 (20.0)
Risk factors	
Any one of the following	35 (87.5)
Hyperlipidaemia	26 (65.0)
Hypertension	25 (62.5)
Smoking	6 (15.0)
Diabetes mellitus	5 (12.5)
Malignancy	
NPC	36 (90.0)
Others†	4 (10.0)
Time between RT and CAS (months)	228.8 ± 100.2 (8-487)
Presence of preoperative neurological symptoms	36 (90.0)

Abbreviations: CAS = carotid angioplasty and stenting; NPC = nasopharyngeal carcinoma; RT = radiotherapy.

\* Data are shown as mean ± standard deviation (range), or No. (%).

† They include hypopharyngeal carcinoma (n=1), laryngeal carcinoma (n=1), oesophageal carcinoma (n=1), and thyroid cancer (n=1).

**Table 2.** Characteristics of the carotid angioplasty and stenting procedures.

Characteristics	Value*
Site	
Right side	21 (52.5)†
Left side	14 (35.0)†
Bilateral	5 (12.5)†
Vessel involved	45 (100)
ICA	22 (48.9)
CCA	21 (46.7)
ICA + CCA	2 (4.4)
Degree of stenosis (%)	75.1 ± 10.8 (50-94.1)
Contralateral carotid occlusion	14 (31.1)
Embolic protection device	37 (82.2)
No. of stent(s) deployed	
One stent	36 (80.0)
Two stents	8 (17.8)
Three stents	1 (2.2)
Stent across carotid bifurcation	33 (73.3)
Residual stenosis >20%	4 (8.9)
Technical success	41 (91.1)

Abbreviations: CCA = common carotid artery; ICA = internal carotid artery.

\* Data are shown as mean ± standard deviation (range), or No. (%).

† % based on No. of patients.

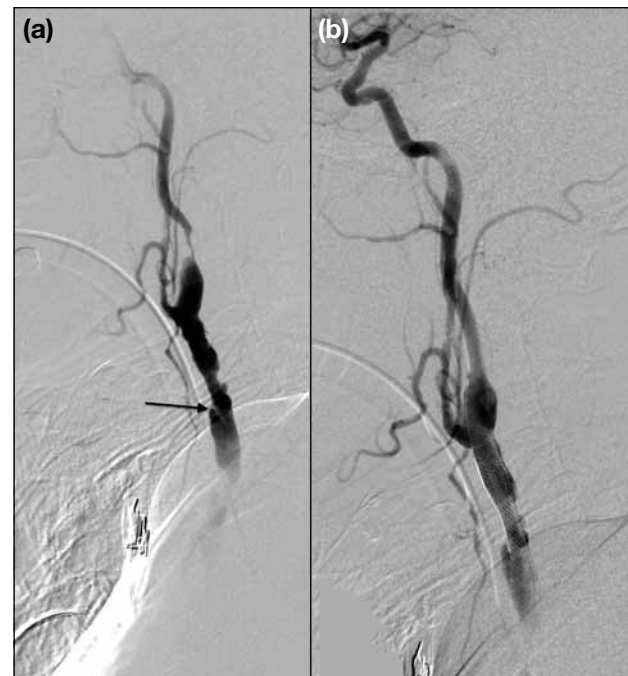
### Early Outcome

There was one (2.2%) procedural complication, with dissection of the left CCA during catheterization for left ICA stenting (Figure 1). It was not associated with additional haemodynamic disturbance or intra-operative stroke. The stenosis and the dissection flap were covered with a total of three Wallstents.

No patient died during the 30-day postoperative period. Three 30-day postoperative neurological events occurred in the 45 CAS procedures, accounting for a postoperative complication rate of 6.7%. These included two cases of minor subarachnoid haemorrhage (SAH) occurring on postoperative day 1 and day 6. The SAH resolved spontaneously in both patients after temporary withholding of the double antiplatelet medications, leaving no added neurological sequelae. One patient had ipsilateral transient ischaemic attack on postoperative day 3 after his left ICA stenting. There was no other postoperative morbidity such as seizure or groin haematoma.

### Long-term Outcome

Follow-up was available for 44 vessels in 39 patients (one patient was lost to follow-up after the 1-month postoperative assessment). The mean follow-up period was 29 months (range, 1-66 months). Four



**Figure 1.** (a) Focal dissection of the left common carotid artery (CCA) [arrow] during catheterization. (b) Three Wallstents were deployed from the proximal internal carotid artery to the common carotid artery to cover both the stenosis and CCA dissection.

(10.3%) patients died during the follow-up (Table 3). One patient died at 8.5 months after CAS of the left CCA due to ipsilateral stroke without evidence of significant restenosis. One patient died from recurrence of metastatic disease at 21.2 months. Two patients died from pneumonia at 1.3 months and 46.8 months after CAS. Four patients (10.3%) had an ischaemic neurological event at a mean interval of 18.8 months (range, 6-41 months) after the procedure, consisting of three cerebral infarcts ipsilateral to the CAS and one amaurosis fugax contralateral to the CAS. Only two of the infarcts were related to significant restenosis.

Restenosis of >70% (Figure 2) was diagnosed in six (13.6%) stented vessels at a mean interval of 17.7 months (range, 3.1-46.7 months) after the procedure. In two of these six cases, restenosis resulted in cerebral infarcts and were symptomatic. The remaining four cases with restenosis were asymptomatic. A second CAS procedure was performed on four cases with restenosis. After the second CAS, two patients were asymptomatic and restenosis-free while one patient died at 15 months and one developed restenosis 10 months after the second CAS. A third CAS procedure was performed on the carotid artery with second restenosis and it was event-free at 11.3 months after the third procedure. Table 3 summarises the outcomes of CAS.

Figure 3 illustrates the survival curves of the 45 stented

vessels. The event-free survival (defined as absence of ipsilateral ischaemic event and restenosis) rates were 92.8% at 6 months, 87.6% at 1 year, and 70.0% at 5 years. The ipsilateral ischaemic event-free survival rates were 97.8% at 6 months, 95.1% at 1 year, and 84.0% at 5 years. The restenosis-free survival rates were 95.0% at 6 months, 92.5% at 1 year, and 74.0% at 5 years.

## DISCUSSION

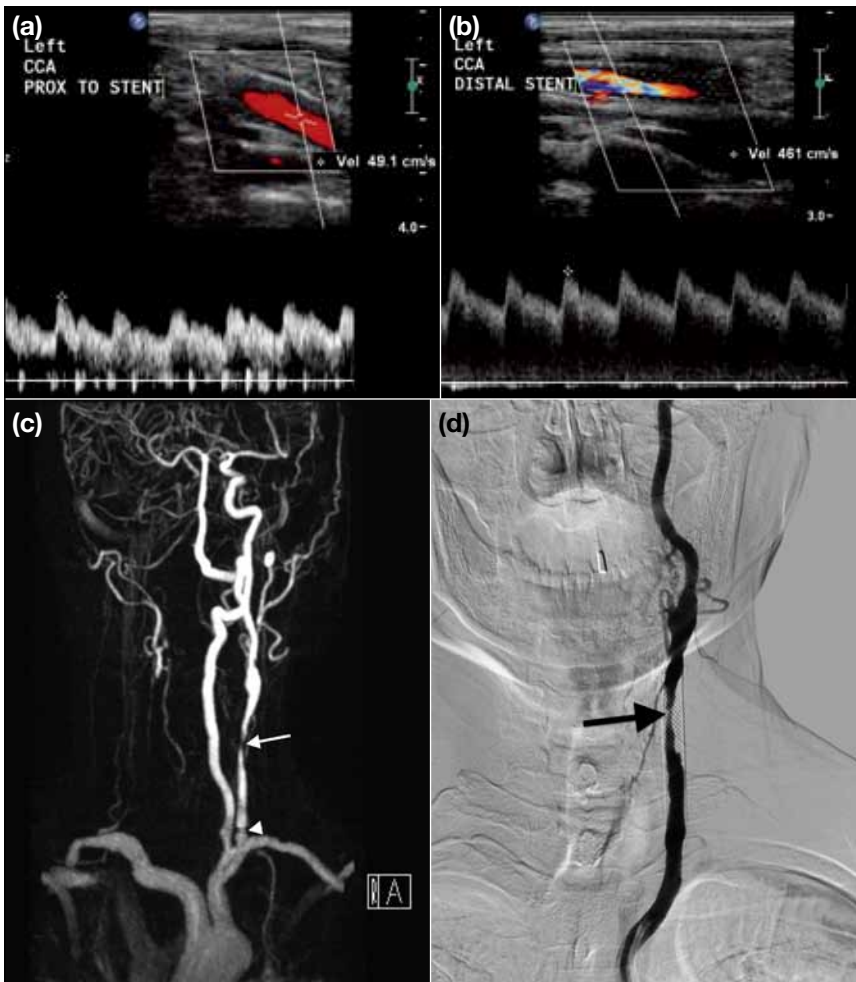
Carotid stenosis is an important and treatable cause of stroke. In 1991, the NASCET demonstrated that carotid endarterectomy was highly beneficial to patients with symptomatic high-grade ICA stenosis.<sup>9</sup> In the past decade, CAS has evolved as an alternative and is increasingly performed for this indication. There are a few multicentre randomised controlled trials comparing the safety and efficacy of carotid endarterectomy with CAS. The long-term follow-up of the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) did not demonstrate significant difference in stroke prevention between the two treatments.<sup>11</sup> The International Carotid Stent Study (ICSS) showed that carotid endarterectomy was safer than carotid stenting in the short term.<sup>12</sup> However, endarterectomy was associated with more cranial nerve injuries and more severe haematomas when compared with CAS.<sup>12</sup> Thus, CAS may be beneficial to radiation-associated stenosis due to the absence of neck incision, avoidance of cranial nerve injury, and less wound complications in the

**Table 3.** Summary of outcomes of carotid angioplasty and stenting.

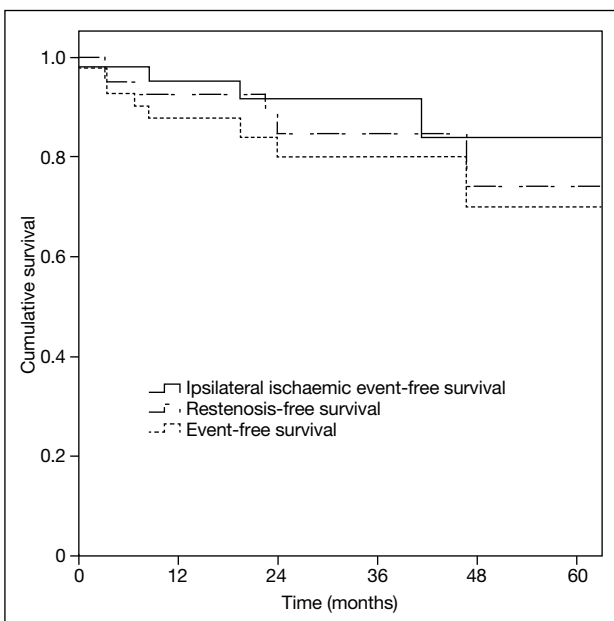
Outcome	Value*
Total No. of vessels stented	45
Procedural complication	
CCA dissection	1 (2.2)
Procedural stroke	0
30-day mortality	0
30-day postoperative complication	3 (6.7)
Minor SAH	2
TIA	1
No. of vessels lost to follow-up	1 (2.2)
Follow-up (months)	29 (1-66)
Long-term mortality	4 (10.3)
Neurological events	4 (10.3)
Infarcts	3
Amaurosis fugax	1
Restenosis >70%	6 (13.6)
Symptomatic	2
Asymptomatic	4
No. of repeat CAS for restenosis >70%	4 (9.1)
Repeat CAS, asymptomatic and restenosis free	2
Repeat CAS and died at 15 months after 2nd CAS	1
Repeat CAS, had restenosis and 3rd CAS performed. Asymptomatic and restenosis free at 11.3 months after 3rd CAS	1

Abbreviations: CAS = carotid angioplasty and stenting; CCA = common carotid artery; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack.

\* Data are shown as No., No (%), or mean (range).



**Figure 2.** (a) Doppler ultrasonography (USG) obtained in left common carotid artery (CCA) proximal to the stent shows a peak-systolic velocity of 49.1 cm/s. (b) Doppler USG obtained in the distal portion of left CCA stent shows a peak-systolic velocity of 461 cm/s, which represents more than tripling of the peak-systolic velocity proximal to the stent and suggests a significant restenosis. (c) Contrast-enhanced magnetic resonance angiogram shows restenosis at distal portion of left CCA stent (arrow). Note the focal band-like signal loss associated with proximal end of the Wallstent (arrowhead). This should not be mistaken as restenosis. Contralateral CCA occlusion is also shown, a common finding in radiation-associated carotid stenosis. (d) Carotid angiogram confirms the distal left CCA stent restenosis (arrow).



**Figure 3.** Kaplan-Meier survival curves illustrating event-free survival, ipsilateral ischaemic event-free survival, and restenosis-free survival for the 45 stented vessels.

irradiated field.<sup>13</sup> Radiation-associated carotid stenosis is a particular concern and relatively common in Hong Kong due to the high prevalence of nasopharyngeal carcinoma in the southern Chinese.<sup>7</sup>

Carotid stenosis has been a known, long-term complication after local irradiation for malignant disease. Yet, the pathogenesis of radiation-induced vessel wall damage has not been fully understood. A combination of different mechanisms has been proposed, including ischaemic necrosis of vasa vasorum, adventitial fibrosis, and accelerated atherosclerosis.<sup>6,14</sup> Recent advances in molecular biology show that the persistent up-regulation of inflammatory markers can be responsible for radiation-induced vascular disease.<sup>15</sup> Nevertheless, traditional cardiovascular risk factors were shown to amplify the hazard of radiation-associated arterial stenosis.<sup>6</sup>

We report our experience on CAS for radiation-associated carotid artery stenosis. In our population, 36

(90%) out of 40 patients had a history of irradiation for nasopharyngeal carcinoma, which is the most common head and neck cancer in Hong Kong.<sup>3</sup> With local studies showing the unique features and pattern of involvement of carotid stenosis after radiotherapy for nasopharyngeal carcinoma,<sup>16,17</sup> this study is different from similar studies performed in Europe and the US where a history of irradiation for laryngeal cancer is more common in patients undergoing CAS.<sup>14,18</sup>

The degree of carotid stenosis correlates with post-radiotherapy duration.<sup>6</sup> In our series, the mean interval from radiotherapy to CAS was 228.8 months, which is comparable to a similar published series.<sup>18</sup> Most patients (90%) in our study had cerebrovascular symptoms whereas 78% (14/18) of patients with carotid stenosis in another similar study conducted by Ting et al<sup>19</sup> were symptomatic. The mean interval from radiation to CAS was 144 months in the study by Ting et al.<sup>19</sup> The difference in the time intervals between the two series suggests there may be a potential time lag between the development of significant carotid stenosis and neurological symptoms. Although the optimal management of asymptomatic carotid artery stenosis remains unclear,<sup>20</sup> this suggests that follow-up at closer intervals may provide an opportunity for medical treatment and consideration of earlier intervention in patients with radiation-associated carotid stenosis.

Evidence suggests that radiation-associated carotid artery stenosis is more extensive and involves the long segment of the CCA, which is not a 'typical' location of atherosclerotic lesions.<sup>21</sup> Significant CCA stenosis is also more prevalent in patients with symptoms of cerebrovascular insufficiency.<sup>6</sup> In our study, 24/45 (53%) patients with carotid artery stenosis showed CCA involvement.

With a 2.2% procedural complication rate without permanent neurological sequelae, 0% of procedural stroke rate, 0% of 30-day mortality rate, and 6.7% of 30-day complication rate without permanent neurological sequelae, our results of CAS for radiation-associated carotid stenosis are considered satisfactory, safe, and comparable with CAS in high-surgical-risk patients.<sup>22</sup> Considering long-term ipsilateral ischaemic neurological events, our results are not inferior to the CAVATAS population, with a cumulative 5-year incidence of 16%.<sup>11</sup> This rate is consistent with that from a previous study showing no significant difference in major adverse events between CAS for atherosclerotic

and radiation-associated carotid stenosis.<sup>23</sup>

A unique feature in our study was the high proportion of patients (31.1%) with contralateral carotid artery occlusion which aligns with the rates in other post-radiation studies. For example, contralateral carotid artery occlusion rate was 25% in the study by Cheng et al<sup>16</sup> and 12% in the study by Favre et al.<sup>14</sup> This group of patients is often under-represented in large multicentre randomised controlled trials for CAS, including ICSS.<sup>12</sup> As endarterectomies in patients with contralateral carotid occlusions have been reported to have increased perioperative morbidity and mortality,<sup>24</sup> CAS theoretically has the advantages of decreased ischaemia time and avoidance of shunt placement. Furthermore, the procedure is performed without sedation or anaesthesia. However, a recent review concluded that contralateral occlusion is not a clinically important reason for choosing CAS over endarterectomy.<sup>25</sup> This study,<sup>25</sup> however, has the drawback of being a retrospective review of a small group of patients (n=57) and short-term follow-up (mean, 28 months). More data are needed for the optimal management in this subgroup of patients.

Cerebral protection devices may decrease the risk of procedural stroke, but evidence is conflicting. Two early multicentre studies, one using Nitinol stent and the SPIDER Embolic Protection System (CREATE Trial) and another one using Wallstent and Filterwire Embolic protection System (BEACH trial) showed that the outcomes in high-surgical-risk patients were promising: CAS using cerebral protection devices was not inferior to endarterectomy.<sup>22,26</sup> The findings were consistent with those of the SAPPHIRE study.<sup>27</sup> However, data from the ICSS study showed cerebral protection devices did not protect against periprocedural stroke.<sup>28</sup> In our centre, the use of cerebral protection device was at the discretion of the operators, with a utilisation rate of 82.2%. In the recent years, we are in favour of using cerebral protection based on our past observations of captured emboli in the filter after retraction of the devices.

In addition to demonstrating good safety profile, the long-term patency rate of CAS in radiation-associated stenosis was satisfactory in our study. Restenosis, defined as >70% stenosis according to NASCET criteria, had a cumulative incidence rate of 7.5% at 1 year and 26% at 5 years in our study. In comparison, a large retrospective study of CAS for radiation-associated stenosis had a 5-year cumulative restenosis



(50% stenosis) rate of 39.8%.<sup>14</sup> In the CAVATAS population, the 5-year cumulative restenosis rates were 16.6% for >70% stenosis and 36.6% for >50% stenosis.<sup>29</sup> A higher >70% restenosis rate was observed for CAS in radiation-associated stenosis. Despite this discrepancy, the CREST study group showed similar restenosis rates with CAS and endarterectomy.<sup>30</sup>

## CONCLUSION

We demonstrated that CAS is safe in patients with radiation-associated carotid artery stenosis. The long-term clinical outcomes of ischaemic neurological events and restenosis are satisfactory.

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