Cerebral Bypass Surgery: Level of Evidence and Grade of Recommendation

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Abstract *Background and aims.* Cerebral bypasses are categorized according to function (flow augmentation or flow preservation) and to characteristics: direct, indirect or combined bypass, extra-to-intracranial or intra-to-intracranial bypass, and high-, moderate- or low-capacity bypass. We critically summarize the current state of evidence and grades of recommendation for cerebral bypass surgery.

Methods. The current indications for cerebral bypass are discussed depending on the function of the bypass (flow preservation or augmentation) and analyzed according to level of evidence criteria.

Results. Flow-preservation bypass plays an important role in managing complex intracranial aneurysms (level of evidence 4; grade of recommendation C). Flow-preservation bypass is currently only very rarely indicated in the treatment of cerebral tumors involving major cerebral arteries (level of evidence 5; grade of recommendation D). The trend has evolved in favor of partial resection and radiotherapy. To preserve the flow, the bypass is always a direct bypass.

Flow-augmentation bypass is currently recommended for Moyamoya patients with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C) and patients with hemorrhagic onset (level of evidence 1B; grade of recommendation A). Flow-augmentation bypass is currently not recommended for patients with recently symptomatic carotid artery occlusion, even in the setting of compromised cerebral hemodynamics (level of evidence 1A; grade of recommendation A), but may be considered in patients with hemodynamic failure and recurrent medically refractory symptoms as a final resort (level of evidence 5; grade of recommendation D).

Conclusions. The results of recent randomized clinical trials narrow the indication for cerebral bypass in the setting of ischemic cerebrovascular disease. However, cerebral bypass is still very useful for managing complex intracranial aneurysms (not amenable to selective clipping or endovascular therapies) and is the only treatment option for managing symptomatic patients with Moyamoya vasculopathy and impaired brain hemodynamics.

Keywords Cerebral bypass · Cerebral revascularization · Evidence-based medicine · Grades of recommendation · Indications · Level of evidence

Background

In current neurosurgical practice, different types of bypasses can be distinguished. According to their function, cerebral bypasses can be classified into “flow-augmentation” and “flow-preservation” [1, 2] (Table 1).

The aim of a flow-augmentation bypass is to restore blood flow to a hypoperfused brain territory in order to avoid strokes in patients with symptomatic steno-occlusive diseases of major cerebral arteries [2, 3].

The aim of a flow-preservation bypass is to replace blood flow to a brain territory previously perfused via a major vessel, the sacrifice of which is necessary to treat an underlying disease (such as an aneurysm) [2, 4, 5].

Bypass surgery is categorized into direct, indirect, and combined procedures. A direct bypass consists of a direct microvascular anastomosis between a donor artery (for instance the superficial temporal artery [STA]) and an intracranial recipient artery, and instantly delivers blood flow to the brain [2–4, 6, 7]. Depending on the choice of the donor artery, direct bypass is classified as extra-to-intracranial (EC-IC) or intra-to-intracranial (IC-IC). Furthermore, the donor and the recipient artery can be anastomosed with or without graft interposition, depending on the interposition or not of a

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Table 1 Bypass types

Function of bypass	*Flow-augmentation*		
	Flow-preservation		
Type of revascularization	*Direct bypass*	EC-IC bypass	No graft interposition
			Graft interposition
		IC-IC bypass	No graft interposition
			Graft Interposition
	Indirect bypass	EMS	
		EDMS	
		EAS	
		EMAS	
		EDAMS	
		EDAS	
		EDPS	
		Multiple burr-holes	
		Omental transplantation	
	Combined bypass	Direct + indirect bypass procedures	
Characteristics of the anastomosis	*Type*	Occlusive (conventional)	
		Non-occlusive (ELANA)	
	Anatomy	End-to-side	
		End-to-end	
		Side-to-side	
Capacity	*Low* (<50 mL/min)		
	Intermediate (50–100 mL/min)		
	High (>100 mL/min)		

EAS encephalo-arterio-synangiosis, *EC-IC* extra-to-intracranial, *EDAMS* encephalo-duro-arterio-myo-synangiosis, *EDAS* encephalo-duro-arterio-synangiosis, *EDMS* encephalo-duro-myo-synangiosis, *EDPS* encephalo-duro-periosteal-synangiosis, *ELANA* excimer laser assisted non-occlusive anastomosis, *EMAS* encephalo-myo-arterio-synangiosis, *EMS* encephalo-myo-synangiosis, *IC-IC* intra-to-intracranial

vascular graft (arterial or venous) [2]. The bypass is traditionally named according to the donor and the recipient vessels (e.g., STA to middle cerebral artery [MCA] bypass) [2, 4, 8]. Direct bypass procedures can be further categorized according to the amount of flow (capacity) provided: low (<50 mL/min), intermediate (50–100 mL/min) or high (>100 mL/min) capacity (see Table 1) [2, 5]. It is important to match the flow to demand, that is, the bypass must supply adequate flow for the needs of the vascular territory that is revascularized.

Indirect bypasses rely on the overlay of vascularized tissue (e.g., muscle, dura, pericranium, omentum) onto the cerebral cortex. The aim is to promote neoangiogenesis over time and achieve delayed revascularization [2, 7, 9, 10].

Combined bypass consists of the "combination" of direct and indirect bypass in the same surgical session [2, 3].

To *preserve* flow, the bypass must be a direct bypass and needs to be performed before permanent occlusion of the vessel. To *augment* flow, direct, indirect, and combined techniques can be applied.

Herein we summarize the current state of evidence and discuss the grades of recommendation for cerebral bypass surgery, using the "Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence" for grading levels of evidence and recommendations (http://www.cebm.net).

Flow-Preservation Bypass

Bypass surgery plays an important role in managing complex intracranial aneurysms not amenable to endovascular therapy or selective clip reconstruction [4]. The treatment of such lesions may in fact require vessel occlusion or "trapping," which involves sacrifice of the artery bearing the aneurysm and/or efferent arteries [2, 4, 11]. The goal of any aneurysm treatment is, however, both aneurysm exclusion and preservation of blood flow to the brain. Therefore, bypass is essential to replace the flow provided by the sacrificed artery [4, 11]. In flow-preservation bypass surgery, a key point is that the bypass has to match the flow of the sacrificed artery: intraoperative quantitative flow measurements allow confirmation of flow matching [2, 4, 12].

The type of bypass performed in this setting is always a direct bypass in order to deliver the flow instantly to the involved territory. By varying the bypass construct (i.e., end-to-side, end-to-end, or side-to-side anastomosis or single or double bypass), the bypass can be customized to the intracranial angioanatomy [2, 4, 5, 11, 13, 14]. Complex aneurysms are rare lesions and their variety and heterogeneity do not lend themselves to randomized clinical trials (RCTs) [2]. The utility of the bypass for managing complex intracranial aneurysms has been demonstrated primarily by many case series (level of evidence 4; grade of recommendation C—see Table 2) [4, 5, 14, 15].

Radical removal of cerebral tumors involving the proximal brain vasculature may be impossible without sacrificing a major artery and replacing it with a bypass [2, 16]. The risk-benefit ratio for complete tumor resection combined with a bypass or partial resection has evolved toward partial resection and adjuvant therapy (radiotherapy or chemotherapy) [2, 16, 17]. The flow-preservation bypass for tumors has substantially declined in frequency during the past few decades. Bypass surgery can be considered only in very select cases, and has to be balanced against whether the benefit of radical

Table 2 Current indications for cerebral bypass: level of evidence

Bypass role	Indication	Bypass indicated	Level of evidence	Grade of recommendation	RCT
Flow-preservation	Complex Aneurysms[a]	Yes	4	C	N.A.
	Tumors	Rarely	5	D	N.A.
Flow–augmentation	Moya ischemic	Yes	4	C	/
	Moya hemorrhagic	Yes	1B	A	Yes
	Symptomatic cerebrovascular atherosclerotic steno-occlusive disease	No[b]	1A	A	Yes

The "Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence" has been used for grading levels of evidence and recommendations (http://www.cebm.net)
N.A. not applicable
[a]Complex aneurysms not amenable to direct clipping or definitive endovascular therapy
[b]May be indicated in select cases presenting with ongoing hemodynamic symptoms (postural or with blood pressure variations) despite maximal medical management or patients having acute stroke with evidence of persistent oligemic brain tissue at risk of infarction (penumbra)

resection plus arterial sacrifice and bypass outweighs the risks in terms of improving survival with good quality of life. Cerebral tumors involving the proximal brain vasculature (e.g., skull base tumors) are also rare: the variety and heterogeneity of these lesions preclude RCTs. Only a few case series and expert opinions are available (level of evidence 5; grade of recommendation D—see Table 2) [2, 15, 18, 19].

Flow-Augmentation Bypass

Bypass surgery is the only effective treatment for managing patients with symptomatic Moyamoya vasculopathy and impaired brain hemodynamics. Bypass surgery has been shown to decrease both ischemic and hemorrhagic stroke rates [2, 3, 10, 20].

Direct, indirect, and combined bypass procedures are used for treating Moyamoya [10, 21]. There is no definitive consensus on which procedure is superior [9, 10]. Traditionally, direct or combined bypass is used in adults, while indirect or combined bypass is applied in children [2, 10, 21].

The most common direct bypass is the STA-MCA bypass [2, 3, 21]. Among the indirect techniques, the following can be considered: encephalo-myo-synangiosis (EMS) [2, 3], encephalo-duro-myo-synangiosis (EDMS) [3], encephalo-arterio-synangiosis (EAS) [22], encephalo-myo-arterio-synangiosis (EMAS) [23], encephalo-duro-arterio-myo-synangiosis (EDAMS) [24], encephalo-duro-arterio-synangiosis (EDAS) [25], encephalo-duro-periosteal-synangiosis (EDPS) [3], multiple burr-holes [26], and omental transplantation [27].

Combined bypass offers the advantages of direct and indirect methods. However, the procedures are somewhat more complex and time-consuming [2, 3, 10].

There are no RCTs on the value of bypass surgery for prevention of ischemic stroke and cognitive deterioration in Moyamoya patients. However, there are a number of observational studies which strongly indicate that bypass benefits these patients [10, 28, 29] compared to natural history; there is an unfavorable annual ischemic stroke rate in untreated patients (up to 13.3%) [30] and a high rate of disease progression with subsequent symptom occurrence in non-surgically treated hemispheres [2, 31]. In light of existing data, an RCT to test bypass surgery efficacy for prevention of ischemic stroke recurrence and cognitive deterioration in symptomatic Moyamoya patients is unlikely be performed [2, 10, 28, 29] because of a lack of equipoise. Based on existing observational studies, surgery is routinely recommended for children and adults with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C—see Table 2) [2, 3, 10, 15, 28, 29, 32].

As for hemorrhagic Moyamoya disease (MMD), bypass surgery has RCT evidence demonstrating its efficacy in preventing recurrence of hemorrhagic stroke in patients with MMDs [20]. Although statistically marginal, the Japanese Adult Moyamoya Trial showed that direct (or combined) bypass surgery for adult patients with hemorrhagic MMD reduces the rebleeding rate and improves patient prognosis during the 5 years following enrollment (level of evidence 1B; grade of recommendation A – see Table 2) [15, 20]. Bypass is thought to improve cerebral hemodynamics, and reduce the hemodynamic stress on, the rupture-prone fragile Moyamoya collateral vessels [20].

The topic of flow-augmentation bypass in patients with symptomatic cerebrovascular atherosclerotic occlusion of extracranial or intracranial major arteries has been extensively debated in the past [33–35]. The main question has been whether STA-MCA bypass (plus medical therapy) benefits patients with symptomatic cerebrovascular atherosclerotic occlusion in comparison to medical therapy.

To answer this question, RCTs have been conducted. The "*EC-IC Bypass Trial*" [33], the first prospective RCT in this field, published in 1985, showed no significant advantage of bypass surgery in reducing the incidence of fatal and non-fatal ischemic strokes [33, 36]. This study was hotly debated [37]: among the various criticisms, the most important related to the lack of hemodynamic criteria used to identify and select high-risk patients who might benefit from a bypass [2].

A Cochrane review [38], published in 2010, reported the results of 21 trials (2 randomized and 19 non-randomized studies) for patients with symptomatic carotid occlusion. Bypass was shown to be neither superior nor inferior to medical care alone [2, 38].

The "*Carotid Occlusion Surgery Study* (*COSS*)" [35] is an RCT whose results were published in 2011. In this study, patients were selected based on very strict hemodynamic criteria, to identify those high-risk patients who might benefit most from bypass [36, 39, 40]. However, STA-MCA bypass (plus medical therapy) was shown to provide no clinical benefit over medical therapy alone [2, 35].

An ancillary study to COSS, the "*Randomized Evaluation of Carotid Occlusion and Neurocognition*" *(RECON) Trial* [41] tested neurocognition at 2 years in COSS patients and was unable to identify a benefit of bypass when compared to medical therapy alone [41].

Both EC-IC Bypass Trial and COSS have generated level I evidence indicating no benefit of bypass for patients with recently symptomatic carotid artery occlusion (in comparison to medical therapy alone) [33, 35, 36]. Bypass failed to show benefit both because medical therapy performed better than in the past and because of the relatively high complication rate in the perioperative period (most of which was non-bypass related) potentially due to the fragility of these flow-compromised patients [2]. Bypass is therefore currently not indicated for these patients (level of evidence 1A; grade of recommendation A) [2, 15, 35, 41].

However, there are subcategories of patients not included in these RCTs (EC-IC Bypass trial and COSS) for whom flow-augmentation bypass could still be of benefit and may be used as a last resort to avoid disabling strokes despite optimal medical and interventional management [2, 42]: (1) patients presenting with ongoing hemodynamic symptoms (postural or with blood pressure variations) and (2) patients having acute stroke with evidence of persistent oligemic brain tissue at risk of infarction (penumbra).

Currently, two other studies are underway. One, "*Carotid and Middle Cerebral Artery Occlusion Surgery Study*" *(CMOSS)* in China (ClinicalTrials.gov NCT01758614), and the other, "*EDAS (Surgical) Revascularization in patients with Symptomatic Intracranial Arterial Stenosis (ERSIAS)*" in the USA. Both may give new insights into the role of direct and indirect bypass, respectively (ClinicalTrials.gov NCT01819597).

Conclusion

Cerebral bypass still represents an important treatment option for managing specific cerebrovascular conditions.

Flow-preservation bypass plays an important role for managing complex intracranial aneurysms (level of evidence 4; grade of recommendation C). Flow-preservation bypass is only very rarely indicated in the treatment of cerebral tumors involving major arteries (level of evidence 5; grade of recommendation D), where the trend has evolved in favor of partial resection and radiotherapy. To preserve flow, the bypass is always a direct bypass.

Flow-augmentation bypass is currently recommended for Moyamoya patients with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C) and Moyamoya patients with hemorrhagic onset (level of evidence 1B; grade of recommendation A). Flow-augmentation bypass is currently not recommended for patients with recently symptomatic carotid artery occlusion failure of cerebral hemodynamics (level of evidence 1A; grade of recommendation A), but may be considered in select patients with refractory hemodynamic symptoms (level of evidence 5; grade of recommendation D).

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