Original Article

Utility of cerebral oximetry in balloon mitral valvotomy and its correlation with post-procedure neurological complications: A pragmatic prospective observational study

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ABSTRACT

Background and Aims: Neurological complications (NCs) are significantly associated with reduced regional cerebral saturation (rSO_2) in patients undergoing cardiac surgeries, as assessed with cerebral oximetry (COx). However, limited evidence is available in patients undergoing balloon mitral valvotomy (BMV). Thus, we evaluated the utility of COx in patients undergoing BMV, the incidence of BMV-related NCs and the association of >20% reduction in rSO_2 with NCs. **Methods:** This pragmatic, prospective, observational study was performed after ethical approval, over November 2018 to August 2020, in the cardiology catherization laboratory of a tertiary care hospital. The study involved 100 adult patients undergoing BMV for symptomatic mitral stenosis. The patients were evaluated at initial presentation, pre-BMV, post-BMV and 3 months after the BMV. **Results:** The incidence of NCs was 7%, including transient ischaemic attack (n = 3), slurred speech (n = 2) and hemiparesis (n = 2). A significantly greater proportion of patients with NCs had a > 20% decrease in the rSO_2 (P value = 0.020). At >20% cut-off, the COx had a sensitivity and specificity of 57.1% and 80%, respectively, in the prediction of NCs. Female sex (P value = 0.039), history of cerebrovascular episodes (P value < 0.001) and number of balloon attempts (P value < 0.001) were significantly associated with NCs. Patients with and without NCs had a significantly greater post-BMV mean % change in rSO_2 than pre-BMV (both right and left sides), but the magnitude of mean % change was greater in those with NCs. **Conclusions:** COx alone has low sensitivity and specificity in the prediction of NCs and cannot reliably predict the development of post-BMV NCs.

Key words: Brain, cardiac surgery, mitral valve stenosis, oximetry, postoperative cognitive dysfunction, cerebral oximetry, balloon mitral valvotomy, regional cerebral saturation

INTRODUCTION

In India, mitral stenosis (MS) of rheumatic origin is a social health issue. In the majority of the patients with haemodynamically significant MS, balloon mitral valvotomy (BMV) is preferred over surgical mitral commissurotomy. It relieves the symptoms by decreasing the mitral valve gradient and raising the mitral valve area.[1] However, it is associated with neurological complications (NCs), including transient ischaemic attack (TIA) and cerebrovascular episodes (CVE).[2] These complications are the result of systemic embolization of intracardiac air, tissue debris and atrial clots.[3]

Cerebral ischaemia resulting in deranged cerebral oxygen supply/demand ratio can be detrimental. Additionally, intraoperative cerebral ischaemia and cerebral oxygen desaturation have been proposed

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as possible mechanisms of post-operative cognitive dysfunction (POCD).[4] Cerebral oximetry (COx) is a continuous and non-invasive technique to assess regional cerebral oxygen saturation (rSO_2) underlying frontal lobes, which are prone to hypoxic and hypotensive injuries.[5] A fall in rSO_2 by >20% from baseline is reported to be associated with higher risk of post-procedure cognitive dysfunction and longer hospitalisation.[6] Additionally, prevention of cerebral desaturation has been demonstrated to result in reduced major organ dysfunction and shorter hospitalisation.[7]

Numerous studies have assessed the utility of COx in various cardiac surgeries.[8] A study evaluated the role of COx in valvular heart surgery and concluded that COx lacks the ability to predict post-procedure cognitive dysfunction.[9] We hypothesized that COx has an ability to predict peri- and post-operative NCs. However, to the best of our knowledge, none of the available studies have assessed the use of COx in BMV. Thus, the objective of the present study was to evaluate the utility of COx in patients undergoing BMV, incidence of BMV-related NCs and association of >20% reduction in rSO_2 with NCs.

METHODS

This was a prospective, observational study conducted in the cardiac catheterization laboratory of a tertiary care teaching hospital. The study was performed over November 2018 to August 2020 and commenced after approval of the protocol by the Institutional Ethics Committee (approval letter No.-IEC/856/18 dated 23/10/2018) and after obtaining written informed consent from all the participants for participation in the study and use of the patient data for research and educational purposes. The study was carried out as per principles of the Declaration of Helsinki, 2013. The STROBE guidelines were followed.

Adult patients aged ≥18 years, of either sex, with symptomatic MS, undergoing BMV and having a mini-mental state examination (MMSE) score >23 were included in the study. Patients on ventilatory support, with known psychiatric disorders and deranged mentation were excluded.

This pragmatic study involved no alteration in routine clinical practice. A standard institutional protocol for routine pre-anaesthetic check-up and laboratory investigation was followed. A detailed neurological examination including level of consciousness by Glasgow Coma Scale; the cranial nerve examination; motor system for tone, power and reflexes; and sensory system was performed, and findings were noted. Tests for cerebellar functions such as Romberg's test, heel-to-shin test and dysdiadochokinesia were noted. The baseline and pre-anaesthetic cognitive function was assessed with MMSE. In the cardiac catheterization laboratory, standard monitors including electrocardiogram, pulse oximeter and non-invasive blood pressure were used. Before administering sedation, adult sensors of in-vivo optical spectroscopy (INVOS) oximeter system (INVOS™ 5100C Somanetics, Medtronic, Minneapolis, USA) were applied on the right and left sides of forehead. Sedation and analgesia were given as per routine practice to decrease anxiety, tachycardia and pain during procedure and also to comfort the patient. Midazolam 0.02 mg/kg IV and fentanyl 1–2 μg/kg IV were given for sedation and analgesia, respectively. The airway was maintained spontaneously with 2 L oxygen supplementation using nasal prongs. Ramsay sedation scale was used to monitor sedation in patients intraoperatively as well as before commencing the tests for NCs post-BMV. Additionally, oxygen saturation (SpO_2), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP) and rSO_2 were monitored continuously and noted at baseline, post-sedation and post-BMV.

Baseline rSO_2 was cerebral rSO_2 recorded prior to pre-medication. Threshold rSO_2 was defined as a 20% reduction as compared with baseline value. Threshold rSO_2 was documented at various time points along with its duration. At the end of BMV, patients were shifted to the intensive care unit. Once the patient achieved baseline Ramsay sedation score, neurological examination and MMSE were performed to detect any post-BMV neurological deficit. The neurological evaluation was repeated at 3 months to rule out any post-BMV neurological dysfunction. POCD was defined as a drop of 1 standard deviation from baseline MMSE.

During BMV, following parameters were noted: rSO_2 (baseline, and % change both pre-BMV and post-BMV); heart rate; SBP, DBP and MBP; Ramsay sedation score (baseline, pre-BMV (after sedation) and post-BMV); duration of fall in rSO_2; number of balloon inflation attempts during BMV; history of CVE and atrial fibrillation (AF) (as per records); complications during procedure; and any post-BMV NCs.

Methodologically, baseline, pre-BMV and post-BMV were defined as follows: baseline: reading taken on catheterization table before sedation and/or oxygen supplementation; pre-BMV: reading taken just prior to balloon inflation during BMV. In case of multiple balloon inflations, first reading was taken as pre-BMV reading; and post-BMV: reading taken post-balloon inflation and deflation. In case of multiple balloon inflations, the event with maximum fall in rSO2 value was considered as a post-BMV reading.

Sample size was calculated based on the 0.5–1% incidence of post-BMV NCs.[10] At 5% level of significance and allowable error of 8% of the probability of cerebral complication, i.e. 0.01, a sample size of 97 was estimated. To accommodate for drop outs, 100 participants were recruited.

The data was analyzed with SPSS (IBM, Armonk, NY, USA) version 23.0 for Windows. The categorical and continuous variables are represented as frequency (percentage) and mean (standard deviation, SD) or median (interquartile range, IQR), respectively. The association between categorical and continuous variables was assessed with Chi-square test and paired *t*-test or Wilcoxon signed rank test, respectively. A two-tailed probability value of <0.05 was considered as statistically significant.

RESULTS

The mean age of the study population was 35.28 ± 11.45 years. The 59% patients were female. On echocardiography, the mean Wilkin's score, left atrial size, mitral valve area and ejection fraction were 8.82 ± 0.90, 48.30 ± 5.62 mm^2, 0.981 ± 0.24 cm^2 and 56.65 ± 5.64%, respectively. None of the patients had left atrial clot. The post-BMV heart rate (*P* value < 0.001) was significantly higher than the baseline and pre-BMV heart rate. The pre-BMV SBP (*P* value < 0.001) was significantly lesser than the baseline SBP, while no significant difference was noted in post-BMV SBP. Likewise, the MAP, DBP and SpO_2 did not differ significantly (all *P* values > 0.05). Compared to the baseline, right and left mean rSO_2 decreased significantly both at pre- and post-BMV (all *P* value < 0.05). Compared to pre-BMV mean % change in rSO_2, post-BMV mean % change in right and left rSO_2 was significantly greater (both *P* values < 0.001). Both pre- and post-BMV median Ramsay sedation scores were significantly higher than the baseline (both *P* values < 0.001). The median pre- and post-BMV MMSE values did not differ significantly [Table 1].

Perioperatively, seven patients developed NCs. Of these seven patients, three had TIA, and two each had slurred speech and hemiparesis. Three patients had history of AF, and four had history of CVE. Three patients had <20% change in rSO_2, while remaining four had >20% change. Three patients required two balloon attempts, whereas remaining two each required three and four balloon attempts. In all seven patients, the duration of fall in rSO_2 ranged from 5 to 22 seconds [Table 2]. At 3-month follow-up, there were no new onset NCs. Moreover, none of the perioperative NCs progressed or deteriorated.

Twenty-four patients had fall in rSO_2. Duration of fall in rSO_2 ranged from 0 to 30 seconds, and most of patients had a fall in rSO_2 for 6–10 and 11–15 seconds (29.17% each). Of these 24 patients, only 7 (29.17%) developed

Table 1: Comparison of baseline, pre-BMV and post-BMV parameters

Parameters	Intervals	Mean±SD	*P*
Heart Rate (bpm)	Baseline	83.12±12.90	-
	Pre-BMV	82.61±14.34	0.474
	Post-BMV	90.01±17.06	<0.001
SBP (mmHg)	Baseline	117.68±15.29	-
	Pre-BMV	114.54±16.13	<0.001
	Post-BMV	117.88±17.88	0.894
DBP (mmHg)	Baseline	69.80±9.99	-
	Pre-BMV	70.51±11.72	0.430
	Post-BMV	71.55±11.64	0.135
MAP (mmHg)	Baseline	85.72±10.87	-
	Pre-BMV	85.24±12.40	0.518
	Post-BMV	86.97±13.01	0.274
SpO_2 (%)	Baseline	99.45±0.74	-
	Pre-BMV	99.33±0.68	0.164
	Post-BMV	99.33±0.65	0.186
rSO_2 (Right)	Baseline	67.56±8.68	-
	Pre-BMV	65.78±8.66	0.005
	Post-BMV	62.82±9.16	<0.001
rSO_2 (Left)	Baseline	67.59±8.25	-
	Pre-BMV	64.38±9.42	<0.001
	Post-BMV	61.98±10.01	<0.001
% change in rSO_2 (right)	Pre-BMV	2.14±10.97	<0.001
	Post-BMV	6.32±13.87	
% change in rSO_2 (left)	Pre-BMV	4.60±9.43	0.001
	Post-BMV	8.11±11.70	
MMSE	Baseline	29 (28, 30)	1.000
	Post-BMV	29 (28, 30)	
Ramsay sedation score	Baseline	1 (1, 2)	<0.001
	Post-BMV	2 (2, 3)	

BMV: Balloon mitral valvotomy, MMSE: Mini-mental state examination; SBP: Systolic blood pressure, DBP: Diastolic Blood pressure, MAP: MEan Arterial blood pressure, rSO_2: Regional cerebral oxygen saturation, SpO_2: Oxygen saturation

Table 2: Details of patients with neurological complications

Neurological complication	History of AF	History of CVE	% Change in rSO_2	Number of balloon attempts	Duration of fall in rSO_2
TIA	+	+ (TIA)	<20%	4	15 sec
TIA	+	+ (TIA)	<20%	3	5 sec
TIA	-	-	>20%	4	12 sec
Slurred speech	-	-	>20%	2	20 sec
Slurred speech	-	+ (Hemiparesis)	>20%	3	12 sec
Hemiparesis	+	+ (TIA)	>20%	2	22 sec
Hemiparesis	-	-	<20%	2	5 sec

AF: Atrial fibrillation; CVE: Cerebrovascular episodes; TIA: Transient ischaemic attack

NCs and most of them had a fall in rSO_2 for 11–15 seconds (n = 3, 42.86%). Additionally, of 24 patients with fall in rSO_2, four (16.67%) had a decrease in rSO_2 by <20%, while 20 (83.33%) had a decrease of >20%. Of patients with <20% and >20% decrease in rSO_2, majority had a fall in rSO_2 for 0–5 (n = 2, 50%) and 6–10 seconds (n = 7, 35%), respectively [Table 3].

Comparison of NCs with decrease in rSO_2 revealed that a significantly greater proportion of patients with perioperative NCs had a >20% decrease in the rSO_2 (P value = 0.020). At 20% cut-off, the COx had a sensitivity and specificity of 57.1% and 80%, respectively, in the prediction of NCs [Table 4].

Evaluation of patients with perioperative NCs revealed that female sex (P value = 0.039), history of CVE (P value < 0.001) and number of balloon attempts (P value < 0.001) were significantly associated with NCs, while history of AF was not significantly associated with perioperative NCs (P value = 0.076) [Table 5].

Patients with perioperative NCs had a significantly greater % change in post-BMV rSO_2 values on both right (P value = 0.001) and left side (P value = 0.013). Similar results were seen in patients who did not have NCs (right side, P value = 0.002; and left side, P value = 0.007). However, % change in patients with perioperative NCs was much higher as compared to the those who did not have NC [Table 6].

Table 3: Comparison of duration of fall in rSO_2 with decrease in rSO2 values and post-BMV neurological complications

Duration of fall of rSO_2	*n* (%)	Neurological complications		Decrease in rSO_2 values	
		Present	Absent	<20%	>20%
0-5 sec	4	2	2	2	2
6-10 sec	7	0	7	0	7
11-15 sec	7	3	4	1	6
16-20 sec	4	1	3	1	3
21-25 sec	1	1	0	0	1
26-30 sec	1	0	1	0	1
Total	24	7	17	4	20

BMV: Balloon mitral valvotomy; rSO_2: Regional cerebral oxygen saturation; sec: Seconds

DISCUSSION

In the present study, the incidence of NCs was 7%. A significantly greater proportion of patients with NCs had a >20% decrease in the COx values. Though patients with and without NCs had a significantly greater post-BMV mean % change in COx than pre-BMV (both right and left side), the magnitude of mean % change was greater in those with NCs.

Overall, BMV is a safe procedure with high success rate, especially in those with optimal valve morphology as evaluated with echocardiography score.[10] BMV results in reduced incidence of NCs in patients with rheumatic heart disease. It enhances the left atrial appendage (LAA) function and decreases the chances of future thromboembolic complications.[11] However, BMV is demonstrated to be associated with post-procedure NCs.[10,12,13] Throughout the study, seven patients developed NCs, including TIA (n = 3), slurred speech (n = 2) and hemiparesis (n = 2). All but one complication developed in the immediate post-BMV period and resolved spontaneously. Slurred speech and hemiparesis lasted for around 6 and 24 hours, respectively. One patient developed TIA just before the follow-up visit at 3 months which resolved spontaneously.

Cardiac surgeries are associated with a critically low initial rSO_2 or a low value not responding to treatment. An absolute rSO2 value less than 50% or a greater than 20% drop from baseline rSO2 is common intervention trigger.[14] Both right and left mean rSO_2 values were found to decrease significantly both at pre- and post-BMV relative to baseline. Additionally, the magnitude of mean % change in rSO_2 was greater in patients with NCs than those without NCs. Though the decrease in mean rSO_2 was statistically significant, it did not attain clinical significance as the mean decrease was <20%. This may be attributed to the immediate change in dynamics of cardiac function and circulation both intra- and post-BMV.

An increase in the duration of fall in rSO_2 is significantly associated with the NCs.[15] Twenty-four patients had fall in rSO_2. However, only seven developed NCs. Only four of these patients had a >20% fall in rSO_2. Additionally, a significantly greater proportion of patients with NCs had a >20% fall in rSO_2. These findings suggest that not all patients with fall in rSO_2 develop NCs, but patients with >20% fall are significantly more susceptible to develop post-BMV NCs. One patient with a fall in rSO_2 for 5 seconds developed NC, while another patient with a fall in rSO_2 for 30 seconds did not develop NC. Though the longer duration of fall in rSO_2 is clearly related to the NCs, in the present study, the duration of fall was within the acceptable range for BMV. This highlights the absence of NCs in the remaining patients with fall in rSO_2.

Increase in the number of balloon inflation attempts was found to be significantly associated with higher incidence of NCs. Two of three patients (66.66%) with four balloon inflation attempts developed NCs. The incidence of NCs in patients who had less than three balloon inflation attempts was 4.05%.

Table 4: Comparison of neurological complications with decrease in rSO_2

Decrease in rSO_2	Neurological complications			*P*
	Yes	No	Total	
<20%	3	75	78	0.020
>20%	4	18	22	
Total	7	93	100	

rSO2: Regional cerebral oxygen saturation

Post-BMV NCs are most commonly a consequence of thromboembolism. Balloon inflation causes mechanical obstruction to the blood flow across mitral valve, LAA blood flow velocity reduces significantly, which may result in complete stasis, leading to acute enhancement of spontaneous echo contrast (SEC) to the highest grade.[16] Balloon deflation again increases the LAA blood flow velocity leading to the reduction or disappearance of SEC. Mechanical obstruction of mitral valve by balloon causes stagnation of blood in LA, which raises the risk of thrombogenesis. The SEC is associated with increased risk of embolism.[17-19] In the present study, one patient showed evidence of SEC during BMV. However, there was no evidence of intra- and post-BMV thromboembolism.

History of CVE was observed to be significantly associated with NCs. Intracranial cerebral arterial disease may be an independent risk factor for NCs following coronary artery bypass graft (CABG) surgery.[20] Around a quarter of patients with intracranial cerebral artery disease have post-CABG NCs, including delirium, amnesia and stroke.[21] Patients with carotid artery disease undergoing cardiac surgery had significantly higher incidence of NCs than those without carotid artery disease.[22,23] Though, in the present study, all the patients had resolved CVE at the time of BMV, the presence of CVE history was found to be a risk factor for post-BMV NCs.

AF is a high-risk factor for thromboembolism and makes patients, particularly elderly, susceptible to stroke.[24] In patients undergoing BMV, AF results in worse immediate and long-term outcome, and lower

Table 5: Comparison of neurological complications with sex, history of atrial fibrillation and CVE, and number of balloon attempts

Parameters	Neurological complications			*P*
	Yes (*n*=7)	No (*n*=93)	Total (*n*=100)	
Sex				0.039
Female	7 (100%)	52 (55.91%)	59 (59%)	
Male	0 (0%)	41 (44.09%)	41 (41%)	
H/o AF				0.076
Yes	3 (42.86%)	15 (16.13%)	18 (18%)	
No	4 (57.14%)	78 (83.87%)	82 (82%)	
H/O CVE				<0.001
Yes	4 (57.14%)	2 (2.15%)	6 (6%)	
No	3 (42.86%)	91 (97.85%)	94 (94%)	
No. of balloon attempts				<0.001
1	0 (0%)	16 (17.20%)	16 (16%)	
2	3 (42.86%)	55 (59.14%)	58 (58%)	
3	2 (28.57%)	21 (22.58%)	23 (23%)	
4	2 (28.57%)	1 (1.08%)	3 (3%)	

AF: Atrial fibrillation, CVE: Cerebrovascular episodes, rSO2: Regional cerebral oxygen saturation

Table 6: Comparison of neurological complications with % change in rSO_2

Neurological complications	% change in rSO_2			*P*
	Side	*n*	Mean±SD	
Yes	Left			
	Pre-BMV	7	-2.00±10.18	0.013
	Post-BMV	7	-16.71±13.05	
	Right			
	Pre-BMV	7	-3.00±7.12	0.001
	Post-BMV	7	-18.71±10.37	
No	Left			
	Pre-BMV	93	-4.82±9.45	0.007
	Post-BMV	93	-7.46±11.38	
	Right			
	Pre-BMV	93	-2.04±22.28	0.002
	Post-BMV	93	-5.43±13.64	

BMV: Balloon mitral valvotomy, rSO_2: Regional cerebral oxygen saturation

success rate.[25] We observed that 18 patients had pre-existing AF and three of them developed NCs. Two had TIA and one had hemiparesis post-BMV. Additionally, one patient had new-onset AF during BMV and developed slurred speech. The history of AF demonstrated a trend towards increasing NCs; however, it did not reach statistical significance.

Pre- and post-BMV median MMSE scores did not differ significantly, and none of the patients had post-BMV cognitive dysfunction. Likewise, a study did not find significant POCD in patients with intraoperative cerebral desaturation, suggesting that factors other than hypoxic neuronal injury are responsible for POCD.[26] However, another study concluded that intraoperatively reduced rSO_2 is associated with early post-cardiac surgery related neuropsychological dysfunction.[27] In yet another study, POCD was found to strongly correlate with intraoperatively reduced rSO_2.[28] Thus, at present, the evidence pertaining to the relationship between POCD and cerebral desaturation remains conflicting.

The NCs were significantly higher in patients with >20% decrease in COx values. However, the sensitivity and specificity of COx at cut-off of 20% was low, i.e., 57.1% and 80%, respectively. Thus, COx alone cannot reliably predict the development of post-BMV NCs. Associated factors including history of CVE and higher number of balloon inflation attempts may predict the risk of post-BMV NCs. Diffusion-weighted magnetic resonance imaging (DW-MRI) has been used in detecting NCs in patients undergoing transcatheter aortic valve replacement. Use of DW-MRI as an additional diagnostic tool in patients with lower rSO_2 values can increase earlier detection of NCs and better management of patients.[29]

The limitations of this study included its single-centre design with relatively small sample size. Coronavirus 2019 pandemic affected the regular follow-up, and 3-month evaluation was performed telephonically and MMSE could not be performed altogether. Additionally, there was absence of long-term follow-up. Thus, long-term NCs could not be assessed.

CONCLUSION

Cerebral oximetry alone has low sensitivity and specificity in the prediction of neurological complications and cannot reliably predict the development of post-Balloon Mitral Valvotomy neurological complications.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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