ORIGINAL RESEARCH

Effect of Percutaneous Tracheostomy on Optic Nerve Sheath Diameter [TONS Trial]

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Highlights

- Like any other surgical procedures, PCT procedure can cause fluctuation in ICP in neurocritically ill patients.
- Noninvasive ICP monitoring by measuring ONSD using bedside ultrasound would be very helpful in these patients who do not have invasive ICP catheter *in situ* due to nonavailability, institutional protocol, or any other reason.
- Measuring ONSD in neurocritically ill patients undergoing PCT procedure would help clinicians for early recognition and management of raised ICP, which would further add on to the overall outcome of the patient.

Abstract

Background: Elective percutaneous tracheostomy [PCT] is the widely performed procedure in neurocritically ill patients as an airway management choice in neurocritical care unit [NICU]. Intracranial pressure [ICP] is a vital parameter to be monitored in these patients while undergoing any surgical procedure including PCT. Optic nerve sheath diameter [ONSD], being a surrogate of ICP, can be done bedside and carries less complications than invasive ICP monitoring. The aim of our study was to assess the effect of PCT on ONSD at different stages of PCT.

Patient and methods: A total of 158 patients with various intracranial pathologies scheduled for PCT in NICU were screened for eligibility in our study. We assessed mean values of ONSD, HR, MBP, and SpO_2 for changes over various time points during PCT using generalized estimating equation (GEE). A *p* value of <0.05 was considered significant.

Results: A total of 135 patients who underwent PCT were analyzed for the study. The values of ONSD changed significantly at different stages of PCT procedure compared to baseline. The baseline ONSD value was 0.39 ± 0.05 cm. ONSD rose significantly to 0.40 ± 0.06 cm during positioning, 0.41 ± 0.06 cm during skin incision, 0.42 ± 0.07 cm during dilatation of tract, 0.41 ± 0.07 cm during insertion of tracheostomy, and 0.41 ± 0.06 cm at the end of the procedure.

Conclusions: PCT leads to a significant rise of ONSD values during all stages of PCT. The available evidences point toward detrimental rise in ICP during PCT. ICP can be monitored noninvasively by measuring ONSD using bedside ultrasound.

Keywords: Intracranial pressure, Neurocritical care, Neurocritically ill, Optic nerve sheath diameter, Percutaneous tracheostomy.

Indian Journal of Critical Care Medicine (2021): 10.5005/jp-journals-10071-23783

Introduction

Critically ill patients in neurointensive care unit [NICU] often require prolonged mechanical ventilatory support. Percutaneous tracheostomy [PCT] on bedside is commonly performed in these critically ill patients.[1] It provides the benefit of better tracheal toileting, early weaning, less airway resistance, less need for sedation, patient comfort, and easy communication.[2,3] Various studies have suggested that early tracheostomy decreases the incidence of pneumonia and overall intensive care unit stay.[4,5] PCT is considered to be a safe procedure with very less complications. The effect of PCT on intracranial pressure [ICP] is still controversial. Only a few studies have investigated the effect of tracheostomy on ICP. Literature search shows studies with conflicting results where some studies show increase in ICP and others with no significant change of ICP during tracheostomy.[6-8] Imperiale et al. in their study showed that PCT does not cause significant rise in ICP at any stage.[8] On the other hand, *TIP trial* conducted by Kleffmann et al. concluded that PCT leads to significant increase in ICP; thus, tracheostomy should only be performed under continuous monitoring of ICP in patients with severe cerebral dysfunctions and critically elevated ICP.[9] We know that optic nerve sheath diameter [ONSD] is often used as a surrogate of ICP.[10,11] It is a noninvasive method of measuring ICP, and many studies have shown its association with raised ICP.[11-14] A wide variation has been reported in the optimal cutoff values, when ONSD was compared with invasive ICP monitoring, ranging

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How to cite this article: Kapoor I, Wanchoo J, Mahajan C, Singhal V, Roy H, Kumar S, *et al*. Effect of Percutaneous Tracheostomy on Optic Nerve Sheath Diameter [TONS Trial]. Indian J Crit Care Med 2021;25(4): 382–387.

Source of support: Nil

Conflict of interest: None

from 4.8 to 5.9 mm.[13,15,16] Kimberly and colleagues have shown an ONSD of >5 mm of diameter correlating with ICP of >20 cm H_2O.[17] However, an intra- and interobserver variability is an important factor during ONSD measurement.

As ONSD, a noninvasive surrogate of ICP, retains the simplicity of procedure, which can be done bedside and carries less complications, we aimed to assess the effect of PCT on ONSD in our clinical setting. We hypothesized that the ONSD assessment would be as effective as invasive ICP, if not better than the ICP monitoring in terms of measurement of changes in ICP during various stages of tracheostomy. The main objective of our study was to see the effect of PCT on ONSD in patients with neurosurgical or neurological diagnosis. Our primary outcome was to assess the effect of PCT on ONSD at different stages of PCT and assess any change in ONSD in comparison with baseline ONSD value.

Methods

Our manuscript adheres to the applicable STROBE guidelines. This multicentric, prospective observational cohort study included patients from two leading centers in the country. After Institutional Ethics Committee approval from both centers [IEC-71/01.02.2019, RP-16/2019, MICR: 1014/2019 (Academic)] and written informed consent from patients, 158 consecutive patients were screened for the study. All patients admitted to NICU were screened for eligibility. Each center enrolled patients for 1 year and collected data using a predefined pro forma. We included adult patients with neurosurgical or neurological diagnosis who are >18 years in age, admitted to NICU undergoing PCT. Our exclusion criteria included patients with age <18 years, presence of coagulopathy, local site infection, difficult neck anatomy, and nonconsenting relatives. Apart from hemodynamic response during PCT, the demographic characteristics, past medical history, including age, gender, weight, total ventilation days till PCT, Glasgow Coma scale (GCS), indication for PCT, any comorbidities, and $PaCO_2$ values were also noted. Data were entered in Excel sheet in a standard manner.

Technique of Performing PCT

PCT was performed by Ciaglia [Blue Rhino] technique using dilator and rotating screw. While carrying out the procedure, the patient was placed into a supine position with slight extension at the neck. Any infusion of sedatives or other medications was continued throughout the procedure, and the patient was ventilated with 100% oxygen. In addition, we gave fentanyl 2 µg/kg, propofol 2 mg/kg, and rocuronium 1 mg/kg. The incision site was marked at first and second cervical level junction just below the cricothyroid membrane. Under aseptic precaution and adequate dilatation of tract, appropriate tracheostomy tube was inserted in the trachea of patient.

ONSD Measurement Technique

ONSD was measured by using 6 to 13 MHz linear probe of ultrasound machine (Sonosite S-Nerve, USA). Ultrasonography was performed by investigators who had sufficient experience of performing this procedure. Patient's eye was covered with a transparent film, and a water-soluble ultrasound transmission gel was applied over the probe. The ultrasound probe was gently placed on the eyelid paying careful attention to exert minimal pressure on the eyeball. The probe was moved slightly from temporal to nasal end to find a suitable angle for displaying the entrance of the optic nerve into the globe. The probe was adjusted to bring optic nerve in the center of ultrasound screen for measurement of size. The diameter was measured 3 mm behind the globe in fixed transverse plain. Baseline optic nerve sheath diameter [ONSD] was measured before the procedure. Subsequently, ONSD was measured at five stages of procedure: (1) positioning, (2) skin incision, (3) dilatation of tract, (4) insertion of tracheostomy tube, and (5) end of the procedure. The value of ONSD taken before positioning was considered as the baseline value. Mannitol was initiated if ONSD rose to >5 mm in diameter during the procedure. An arterial sample was taken before starting the procedure for blood gas analysis. We ensured to maintain normocarbia before starting the procedure and throughout the procedure by maintaining the ventilator setting.

Simultaneously, mannitol if required during the procedure was also noted. Any hemodynamic instability [hypotension (mean blood pressure (MBP) <20% of baseline), hypertension (MBP >20% of baseline), bradycardia (heart rate (HR) <20% of baseline), tachycardia (HR >20% of baseline), and desaturation (SpO_2 <90%)] was noted. Complications, if any, were also noted.

Statistics

Data were analyzed using software STATA 15.0 (College Station TX). Data are expressed as mean (SD) or number (%). The generalized estimating equation (GEE) was used to estimate the continuous parameters such as HR, MBP, and ONSD, over the various time points. The value of *p* less than 0.05 was considered significant.

Results

A total of 158 patients with various intracranial pathologies scheduled for PCT in NICU were screened for eligibility. Out of 158 adult patients, 23 patients were excluded for not meeting the inclusion criteria (Fig. 1). A total of 135 patients who underwent PCT were analyzed for the study (Table 1). Out of 135 patients, PCT was indicated for poor baseline GCS in 43 patients, prolonged ventilation days before PCT in 91 patients, and bilateral vocal cord palsy in one patient. Among various associated comorbidities,

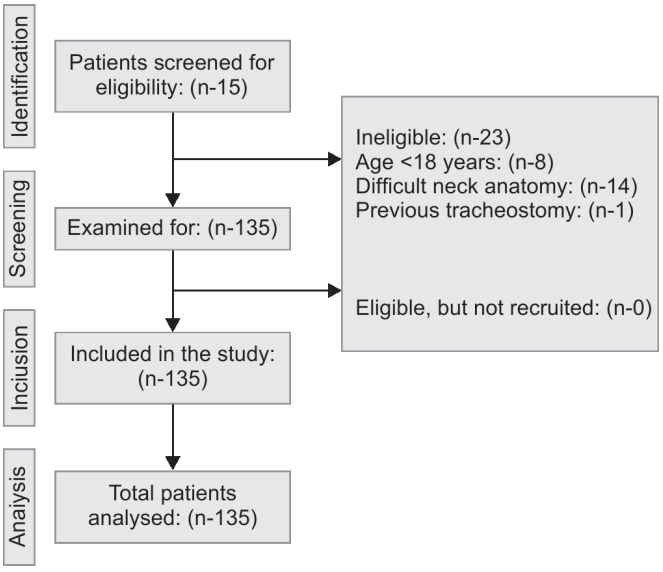

Fig. 1: Strobe flowchart of trial and reasons for exclusion after allocation

Table 1: Showing various intracranial pathologies and associated co-morbidities

Diagnosis	*Patients*
Brain tumor	12
Brain infection	14
Aneurysm	6
Stroke	6
Nontraumatic intracerebral hemorrhage/bleed	23
Traumatic brain injury [TBI]	56
Spinal injury	5 [3 cervical, 1 dorsal, 1 lumbar]
Others	Guillain-Barre syndrome (GBS) [5], cortical venous thrombosis (CVT) [1], infarct [7], encephalopathy [1]
Associated comorbidities	*Patients*
Hypertension	42
Diabetes mellitus	16
Heart disease	12
Respiratory disease	4
Kidney disease	2
Others	SLE [1], HIV/HCV [1], pancreatitis [1], hepatic abscess [1], old CVA [2]
None	53

hypertension and diabetes mellitus were the commonest (Table 1). The age of patients in our study was 44.88 ± 17.42 (years), weight was 67.11 ± 9.15 (kg), duration of mechanical ventilation before tracheostomy was 6.38 ± 3.80 (days), and partial pressure of carbon dioxide [$PaCO_2$] was 33.37 ± 2.31 (mm Hg). The SpO_2 values did not show any significant changes during various stages of PCT. The values of HR, MBP, and ONSD changed significantly at different stages of PCT procedure: (1) positioning, (2) skin incision, (3) dilatation of tract, (4) insertion of tracheostomy tube, and (5) end of the procedure (Figs 2 and 3). The baseline ONSD value was 0.39 ± 0.05 cm. ONSD rose significantly to 0.40 ± 0.06 cm during positioning, 0.41 ± 0.06 cm during skin incision, 0.42 ± 0.07 cm during dilatation of tract, 0.41 ± 0.07 cm during insertion of tracheostomy, and 0.41 ± 0.06 cm at the end of the procedure. Out of 135 patients, five patients showed transient rise in ONSD value >5 mm during different stages of PCT (Table 2). Among them, three patients had a rise in ONSD value >5 mm during dilatation stage, one patient had a rise during both dilatation and insertion stages, and one patient had a rise during insertion stage alone. Therefore, these patients received injection mannitol @ 1 gm/kg. Seven patients had procedure-related complications such as hypotension (5), bradycardia (1), and bleeding (1). Each complication was dealt successfully, and none of them were fatal. Ephedrine was used for hypotension, gauge compression used for bleeding, and pause during procedure corrected bradycardia on its own.

Discussion

The patients in NICU are considered to be more critical and often require ventilator support for prolonged period compared to general patient population. Elective PCT is the widely performed procedure in these patients as an airway management choice in NICU. It is prudent to monitor the effect of this elective procedure on ICP in this set of patients. The literature remains uncertain with results in reference to the effect of PCT on ICP, where in some studies, it has shown to increase the ICP, and in others, it has shown no change in ICP during PCT. In most of the studies, the authors have assessed the effect of PCT on ICP by means of invasive techniques (intraventricular or intraparenchymal catheters). In our study, we assessed the effect of PCT on ONSD (surrogate of ICP), which is technically an easy bedside procedure, is noninvasive in nature, is less time consuming, and has minimal complications compared to invasive techniques of ICP monitoring.

Few studies have investigated the effect of PCT on ICP that too using invasive measurement techniques. Our study is the first of its kind where the effect of PCT on ICP has been assessed using its surrogate, the ONSD. We found a significant increase in ONSD values in comparison with baseline ONSD values at different stages of PCT, which include positioning, skin incision, dilatation of tract, insertion

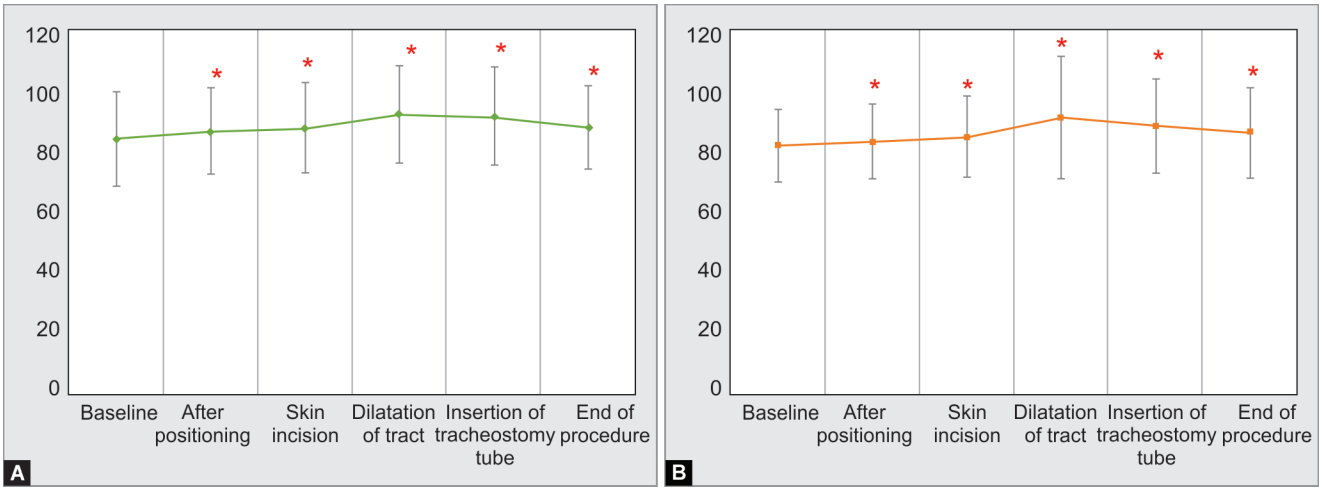

Fig. 2A and B: Hemodynamic responses [Heart rate (HR) in beats/minute, Mean Blood pressure (MBP) in mm Hg] at different stages of percutaneous tracheostomy [PCT]

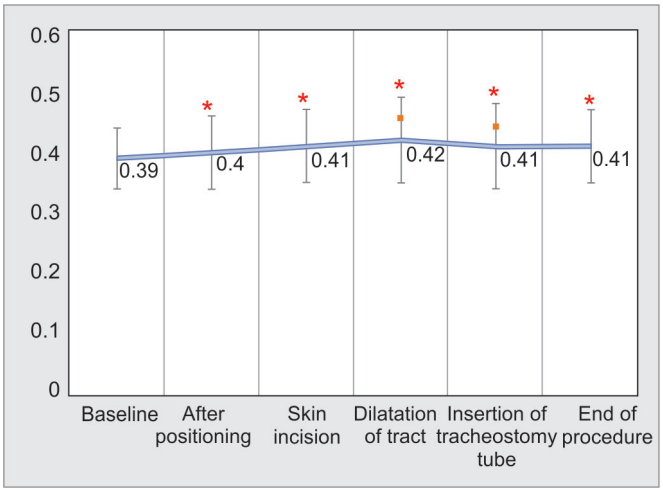

Fig. 3: Optic Nerve Sheath Diameter [ONSD] (in cm) changes at different stages of percutaneous tracheostomy [PCT]

of tracheostomy tube, and end of the procedure. The baseline ONSD value in our study was 0.39 ± 0.05 cm, and maximum rise of ONSD (0.42 ± 0.07 cm) was observed during dilatation of tract. Although rise in ONSD values during all stages of PCT compared to baseline value was statistically significant (but within normal range), the clinical significance of these raised values remains uncertain. Kocaeli et al. reported significant increase in ICP during tracheal cannulation stage while performing PCT in patients with various intracranial pathologies.[6] The ICP rose to 28.4 ± 13.7 cm H_2O from baseline value of 15.1 ± 5.2 cm H_2O in their study. In our study, a significant increase in ONSD values was noted at all stages of PCT including tracheal cannulation stage compared to the baseline value, while maintaining near normocapnia throughout the procedure. The mean $PaCO_2$ value was 33.37 ± 2.38 mm Hg in our study. A lone increase in ICP only during tracheal cannulation is difficult to justify in Kocaeli's study. Since they did not mention the $PaCO_2$ value at baseline as well as during the procedure, the possibility of high $PaCO_2$ levels during tracheal cannulation cannot be ruled out, which could have caused rise in ICP. In *TIP trial* by Kleffmann et al., in comparison with median baseline ICP value of 9 mm Hg, ICP rose significantly to 14 mm Hg during positioning, 16 mm Hg during bronchoscopy, and 18 mm Hg during tracheostomy in patients with acute cerebral dysfunction with the presence of intraparenchymal cerebral pressure measurement.[9] In coherence with their study, our study also shows significant increase in ONSD values at these stages in comparison with baseline ONSD value. Contrary to our study, after the procedure, their ICP normalized and returned to baseline level, whereas in our study, ONSD values did not return to baseline during the study period. Little is known about the factors influencing the ICP during PCT. Duration of PCT procedure could be one of them. In a study by Imperiale et al., the duration of PCT was 10.4 ± 4.9 minutes and there was no significant increase in ICP at all stages of procedure.[8] In TIP trial, the average time for PCT was 17 minutes (range 5–70 minutes) and there was significant increase in ICP values at almost all stages of PCT. We are unsure if duration of PCT has any bearing on the rise in ICP during the procedure. In our study, we did not measure the total duration of PCT. Hence, there could be a possibility that procedure time lasted even longer than TIP trial in our study leading to significantly high ONSD value even at the end of the procedure. Imperiale et al. in their observational study assessed the effect of PCT on patients diagnosed with meningioma, hematoma, subarachnoid hemorrhage, and traumatic brain injury having ICP catheter *in situ*, either intraventricular or parenchymal (Becker-bolt) catheter. They showed that ICP was affected by PCT, but the ICP increase was transitory and mainly confined within the normal ICP range.[8] They credited few factors like appropriate position of the head during tracheostomy leading to a normal cerebral venous outflow, adequate anesthetic depth, and vertical traction of the anterior tracheal wall during the dilation maneuver, etc., that might have decreased airway resistance and thus prevented significant ICP increase during PCT. Use of bronchoscope could be another major determinant able to blunt intracranial sympathetic response during PCT in their study. Though, in our study, we too maintained proper positioning and adequate anesthetic depth, absence of bronchoscope and ventricle traction of anterior tracheal wall during dilatation maneuver might have caused significantly high ONSD values at different steps compared to baseline.

In our study, the baseline HR was 83.94 ± 15.58 beats/minute and baseline MBP was 82.01 ± 11.76 mm Hg. There was significant increase in HR and MBP at all stages of PCT compared to baseline. Not all studies have commented on hemodynamic response during PCT. Kleffmann et al. observed drop in MBP only during positioning for PCT.[9] On the other hand, Imperiale et al. did not find any significant change in MBP during the procedure.[8] About SpO_2, we did not observe any significant change at any stage of PCT and the values remained between 97 and 100% throughout. Kleffmann et al. did not observe any significant changes in SpO_2 before, during, or after the intervention.[9]

Like any other study, our study also has few limitations: (1) The PCT procedure has been reported to be associated with hypercarbia and acidosis, which has been reported to be frequent and may go unnoticed since we used conventional end-tidal carbon dioxide [$EtCO_2$] monitoring during the procedure. Technically, it was not possible to take arterial sample each time at every stage. We did

Table 2: Showing details of patients having ONSD values >5 mm during different stages of PCT

Patient characteristics	*Patient 1*	*Patient 2*	*Patient 3*	*Patient 4*	*Patient 5*
Age (years)	81	20	18	50	41
Gender	Male	Male	Male	Female	Female
Diagnosis	Pontine infarct	TBM	Thalamic SOL	Frontal contusions	ICH
Baseline ONSD	0.47 cm	0.49 cm	0.47 cm	0.46 cm	0.44 cm
Stage of PCT leading to transient rise in ONSD >5 mm	Dilatation [max ONSD = 0.57 cm]	Dilatation [max ONSD = 0.58 cm]	Dilatation [max ONSD = 0.62 cm]	Dilatation and insertion [max ONSD = 0.52 cm]	Insertion [max ONSD = 0.56 cm]

*TBM, tubercular meningitis; SOL, space-occupying lesion; ICH, intracranial hemorrhage; ONSD, optic nerve sheath diameter

baseline blood gas analysis to ensure normocarbia before starting the procedure and throughout the procedure by maintaining the ventilator setting. (2) We did not measure total duration of PCT procedure, which could have provided a new information on association between duration of procedure and ONSD values. Few studies in existing literature have shown association between duration and its effect on invasive ICP values. (3) Intra- and intersubject variability while measuring ONSD values could be another unavoidable limitation of our study. (4) Few patients already on sedative infusion continued during the PCT procedure, could have influenced ONSD value which cannot be negated. (5) Along with ONSD, we did not measure ICP through invasive method as all patients did not have catheter *in situ*.

Overall ONSD changes in our study occurred over all stages of PCT. The result of our study was either in consistence or incoherence with existing studies on literature search. But all of these studies have assessed the effect of PCT on ICP with invasive techniques. Our noninvasive method of ICP monitoring and assessment of the effect of PCT on ONSD makes it a first report that specifically addresses ONSD changes that occur during PCT in NICU patients.

Conclusions

PCT is the common surgical procedure performed in NICU. ICP is a vital parameter to be monitored in neurocritically ill patients while undergoing any surgical procedure including PCT. Evidences are available in the literature that PCT can cause detrimental rise in ICP. Without invasive ICP monitor *in situ*, one can monitor ICP noninvasively by measuring ONSD in these patients using bedside ultrasound. It is feasible to do ONSD scans during ICU procedures, which need ICP monitoring. Clinicians should take necessary preventive precautions while performing PCT in an attempt to avoid secondary insult following rise in ICP in an already injured brain.

Author's Contribution

Indu Kapoor: This author helped in initial study design, patient enrolment, data collection, data analysis, and manuscript preparation.

Jaya Wanchoo: This author helped in patient enrolment and data collection.

Charu Mahajan: This author helped in data collection and revised final draft of manuscript.

Vasudha Singhal: This author helped in revising final manuscript.

Hirok Roy: This author helped in patient enrolment and data collection.

Subodh Kumar: This author helped in patient enrolment and data collection.

Rupali Brahma: This author helped in patient enrolment and data collection.

Chandrakant Prasad: This author helped in patient enrolment and data collection.

Mani Kalaivani: This author helped in statistical analysis.

Hemanshu Prabhakar: This author helped in initial study design, data analysis and revised final draft of manuscript.

Arvind Chaturvedi: This author helped in revising final manuscript .

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