Article published online: 2022-09-20

ORIGINAL ARTICLE

A cost effectiveness based safety and efficacy study of resterilized intra-parenchymal catheter based intracranial pressure monitoring in developing world

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ABSTRACT

Background: The management of traumatic brain injury (TBI) aims to maintain the normal cerebral perfusion in spite of the mass lesions that may occur (haematoma, contusion, and oedema). The monitoring of the intracranial pressure (ICP) is a step in that direction. The intra-parenchymal catheters have the lowest incidence of infection compared to intra-ventricular/subdural catheters with reliable and accurate pressure recordings. The major disadvantage of the intra-parenchymal catheters is the cost, especially in developing nations.

Hypothesis: Resterilized intra-parenchymal strain gauge catheters can be used safely for ICP monitoring without any added risk of meningitis. The reusage of catheters can bring down the costs. Resterilized catheters/equipment have been approved for usage in cardiac usage, but such study on ICP catheters has not been carried out so far in any part of the world.

Methodology: A total of 100 consecutive cases of severe TBI receiving ICP monitoring at a level 1 trauma center of a developing nation were prospectively studied (34 cases had fresh catheters, and 66 had resterilized [using ethylene oxide] catheters).

Observations: The use of reused resterilized catheters was not associated with increased incidence of meningitis or fever (the surrogate marker for infection in this study). Also, there was concordance between the pressure recording of reused catheters and operative finding/subsequent computed tomography scans. These catheters after sterilization could be reused 2–4 times and reliably recorded the ICP (insignificant drift) with no increase in the incidence of meningitis.

Conclusions: Usage of resterilized intra-parenchymal ICP catheters is feasible, safe, efficacious, and cost effective and brings down the cost of monitoring significantly.

Key words: Intra-parenchymal intracranial pressure catheter, resterilized reused catheters, traumatic brain injuries

Introduction

Raised intracranial pressure (ICP) is a common cause of morbidity and mortality in traumatic brain injuries (TBIs). The clinical assessment of raised ICP can be fallacious. Objective measurement of the ICP is desirable prior to aggressively treating it for both ICP and cerebral perfusion pressure based regimens. Brain trauma foundation (BTF) recommends monitoring of ICP in severe TBI (BTF guidelines 3rd edition 2007, Class II evidence).[1] The use of these pressure monitoring devices is restricted by the fear of infection and the cost associated with their use. Though, intraventricular catheters

Access this article online	
Quick Response Code:	Website: www.asianjns.org
	DOI: 10.4103/1793-5482.165785

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How to cite this article: Gupta DK, Bisht A, Batra P, Mathur P, Mahapatra AK. A cost effectiveness based safety and efficacy study of resterilized intra-parenchymal catheter based intracranial pressure monitoring in developing world. Asian J Neurosurg 2016;11:416-20.

are the gold standard for ICP monitoring, but it is technically more demanding to hit the ventricles especially in the setting of post traumatic swollen brains with compressed ventricles. Thus, intra-parenchymal pressure monitoring is practised in our institute as it is technically less challenging.

Hypothesis

Resterilized intra-parenchymal strain gauge catheters can be used safely for ICP monitoring without any added risk of meningitis. The reusage of catheters can bring down the costs. Resterilized catheters/equipment have been approved for usage in cardiac care, but such study on ICP catheters in TBI has not been carried out so far in any part of the world.

Methodology

The study was carried out at a level 1 trauma center of India where a large volume of patients with severe TBI are subjected to ICP monitoring. ICP monitoring was carried out in a total of 534 out of 670 (79.7%) severe head injury admissions in 2012 and in 342 of 590 (58%) severe head injury admissions in 2013. One hundred consecutive patients with TBI who underwent ICP monitoring based on BTF guideliens (2007)[1] were included in the study. All these 100 patients had only intra-parenchymal catheter. Each intra-parenchymal ICP catheter in developing countries costs approximately 400–500 US dollars. The reuse of catheters twice or 3 times would bring down the effective cost of a catheter to one-half to one-third, thereby making the usage cost effective. Only catheters with undamaged tips based on physical inspection were ethylene oxide (ETO) sterilized and were considered for reimplantation later on. Sterility check on efficacy of ETO sterilizer was also performed during this study by taking saline washings of tips at the time of insertion in resterilized catheters (all these catheters were sterile as revealed by culture reports 24 h postinsertion). Strain gauge system with sensor at the tip of intra-parenchymal ICP catheter was used, which was inserted through a twist drill craniotomy (done in the ICU under aseptic precautions) at the right Kocher's point and exited through a separate incision 6 cm apart by subcutaneous tunneling. Prior to insertion, the functioning of the reused catheters was checked by dipping the catheters in normal saline (NS). The patients were catheterized, sedated, ventilated, and started on prophylactic antibiotics. The ICP reading was visible as a numerical value, as well as in the waveform on the patient monitoring system. The choice of new/used catheters was made randomly with a bias toward using previously used catheter if they were available. The treating surgeon made his decisions based on ICP values/trends and clinico-radiological response in each individual case irrespective of whether fresh or resterilized catheter was used. Reading and trends of ICP values were noted in prospectively included continuous cohort of 100 cases irrespective of fresh/reused catheter. No case of catheter blockage was noted in the present series. Patients with raised ICP and/or fresh operable lesions developing on subsequent computed tomography underwent surgery in the form of decompressive craniectomy with or without contusectomy (on the discretion of the operating surgeon). Medical therapy to reduce ICP was restricted to optimizing pCO_2 to 35 mm Hg and osmotherapy with mannitol. In patients with normal ICP the monitoring was continued till it deemed appropriate clinically (maximum being 8 days). All patients who developed fever underwent blood, urine, and tracheal cultures along with complete blood counts and urine microscopic examination. Patients clinical suspicion of meningitis were subjected to cerebrospinal fluid (CSF) analysis by lumbar puncture and culture of the CSF sample. The used catheters in the study were sterilized by ETO using standard protocol of duration of exposure and were packed in airtight sealed plastic bags. The catheters tips after removal were washed in 1 ml NS and this saline was then cultured using standard techniques. Patients with positive cultures (if any) were planned to be treated with appropriate antibiotics as shown by the culture sensitivity. Empiric antibiotics (3rd generation cephalosporins with aminoglycosides are given to all postoperative patients of emergency nonpeneterating head injuries with external ventricular drain [EVD]/ICP catheters/drains for 5 days/2 days after afebrile episode/culture negativity in previously positive culture proven cases in our hospital as per existing protocols). As this was a cohort of patients treated with same antibiotics, the issue of bias for subclinical infections or culture positive cases in view of empirical antibiotic usage in two groups was addressed. Antibiotic policy is uniform for all admitted patients severe head injury patients (operated/nonoperated) in neurointensive ICU in our patients.

Statistical analysis

All statistical analysis was done using Epi Info™ 7 using Fisher's exact test and ANOVA tests, $P < 0.05$ was taken as significant.

Results

A total of 100 patients were enrolled in the study which included 88 male and 12 female patients with age ranging from 1 to 83 years (mean ± 2 standard deviation: 33.09 ± 17 years). The mean Glasgow coma score was 7.66 ± 3.16. New catheters were used in 34 patients and previously used catheters were used in 66 patients. The catheters had been used for 1.42 ± 1.22 times prior to the present implantation with a range of 1–4. The catheters were kept *in situ* till either there was no further need for ICP monitoring or the patients were taken up for surgery/decompressive craniectomy. The mean duration of monitoring was 2.19 ± 1.33 days with a range of 1–8 days [Table 1] and there was no increase in the infection rates with increased duration of monitoring. In this study, there was no extra cost from sterilization of these catheters to hospital as these were sterilized by ETO along with other standard equipments/catheters. There was no extra cost incurred to

hospital from increased use of antibiotics or prolonged stay in reused catheters either. The cost was reduced to one-half to one-third by using the same catheters 2–3 times thereby making the resuage of catheters cost effective for the hospital.

Surgery was performed in 44 patients and 56 were managed conservatively. There was 100% concordance in the ICP recordings and the findings of raised ICP at surgery (tense dura/brain bulge) for both new and previously used catheters. Forty-nine of the patients had a Glasgow outcome score (GOS) of 5, 4 had a score of 4, 20 had a score of 3, 7 had a score of 2, and 20 had a GOS of 1.

Of the 53 patients in this study who had a fever (temperature >37.8°C [100.4 F]), 31 had been operated upon, and 22 were managed nonoperatively. The incidence of fever was higher in the operated patients (70%of the patients with fever), and this was statistically highly significant [Table 2]. However, the use of a previously used catheter [Table 3] was not associated with a higher incidence of fever ($P = 0.2$, not significant).

CSF analysis by lumbar puncture, based on the clinical suspicion of meningitis, was carried out in 15 patients, and meningitis was seen in 5. Four of these had been operated, and one had been managed nonoperatively. In two of these patients, a new catheter had been used and previously used catheter was used in three patients. There was no statistically significant difference in the incidence of meningitis with the use of new or previously used catheters ($P = 0.55$ [Table 4]).

Table 1: Duration of ICP recording for new and previously used catheters

	0-2 days (%)	3-4 days (%)	>4 days (%)	Total
New catheter	18 (53)	14 (41)	2 (6)	34
Previously used catheter	46 (70)	16 (24)	4 (6)	66

P=0.19 (not significant). ICP – Intracranial pressure

Table 2: Incidence of fever

	Afebrile	Fever	Total
Conservative	34	22	56
Surgery	13	31	44
Total	47	53	100

Fisher's exact test *P*=0.0017 (highly significant)

Table 3: Incidence of fever with new/reused catheter stratified for surgery

	Conservative			Surgery done		
	Afebrile	Fever	Total	Afebrile	Fever	Total
New catheter	13	5	18	5	11	16
Perused catheter	21	17	38	8	20	28
Total	34	22	56	13	31	44

Fisher's exact test *P*=0.2068 (not significant)

Only one catheter tip wash culture was positive in which *Staphylococcus aureus*, probably a skin commensal, grew. This patient did not have features of meningitis, so no CSF study was carried out in this case, and the patient had a GOS of 5 at discharge.

When the incidence of fever and meningitis was studied with the use of new or previously used catheters after stratification for surgery the results were not statistically significant [Table 5]. The duration of ICP monitoring did not have any statistically significant difference in the incidence of infection [Table 6].

Although the manufacturers of such devices/catheters recommend single usage, it is not a viable option in developing countries especially when one has to treat a voluminous work load of severe head injured with 4–5 patients (new and old) undergoing ICP monitoring at a time point on a single day in a 20 bedded neurointensive unit. ICP insertion for monitoring was carried out in 534 of 670 severe head injury admissions during the period of the study in our center. All patients wherein resterilized catheters were used showed good waveforms, trends and ICP values which were taken

Table 4: Incidence of meningitis with new/reused catheter

	No meningitis	Meningitis	Total
New catheter	32	2	34
Reused catheter	63	3	66
Total	95	5	100

Fisher's exact test *P*=0.55 (not significant)

Table 5: Incidence of meningitis with new/reused catheter stratified for surgery

	Conservative			Surgery		
	Meningitis	No meningitis	Total	Meningitis	No meningitis	Total
New catheter	0	18	18	2	14	16
Perused catheter	1	37	38	2	26	28
Total	1	55	56	4	40	44

Fisher's exact test *P*=0.2 (not significant)

Table 6: Duration of ICP monitoring and meningitis

Days ICP kept	No meningitis	Meningitis	Total
0	1	0	1
1	36	3	39
2	24	0	24
3	19	2	21
4	9	0	9
5	5	0	5
8	1	0	1
Total	95	5	100

P=0.5066 (not significant). ICP – Intracranial pressure

into consideration while taking decision to surgically or conservatively manage these patients. At our center, we have been routinely using resterilized catheters without any added risk of infection or monitoring issues and able to restrict the cost significantly to one-third to one-fourth without compromising the care, to provide multimodality monitoring in these severely head injured patients.

Discussion

Literature review of over 2253 articles (1980–2013) revealed that ICP monitoring is safe, best performed using a parenchymal monitor or ventricular catheter.[2] Great variability in use of ICP monitoring remains despite the availability of established ICP guidelines. Increased ICP/pattern of increase and ICP refractory to treatment is associated with increased mortality.[2] BEST TRIP trial could be carried out in Latin American countries and the randomization was possible (ICP monitoring vs. no ICP monitoring) only because some centers were not using ICP monitoring as a standard of care in TBI care owing to cost restraints.[3] Cost issue is the major deterrent to do intra-parenchymal pressure monitoring in all parts of the world despite the well-established role of ICP monitoring based approach in TBI care.[3,4] This is compounded in developing nations as majority of subjects do not have insurance covers for health care.

The hypothesis of carrying out this efficacy study was intra-parenchymal ICP monitoring using reused catheters was feasible, efficacious, and safe in neurotrauma patients. Multiple uses of single use medical devices after reprocessing has been approved by the Food and Drug Administration (FDA) and is prevalent in other specialities mainly cardiology where angiography catheters and pacemakers are being reused with no increase in the rates of infection or change in efficacy.[2,5]

The incidence of culture proven meningitis in this study group of TBI patients was 5 (5%), 3 were multiple drug resistant (MDR) *Acinetobacter* spp. and 2 were MDR *Klebsiella* spp. sensitive only to colistin. Four of these patients also had remote site infections and had undergone surgery, both of which are risk factors for meningitis/ventriculitis. Literature reports colonization in intra-parenchymal ICP sensors at 14% (range: 11.7–16.6%) and infection rates of 2.9%.[6-8] In this study, the colonization rate was noted in 1% and meningitis was noted in 5% of cases. However, as four of these patients had undergone surgery and had cultures from other sites positive with the same organism, it is likely that the meningitis occurred in these patients are as a part of bacteraemia and not secondary to ICP monitoring. The other studies reporting infection with catheters had cut the tip for culture but since we were reusing the catheter we used saline wash from the catheter tip for culture with the yield of saline wash cultures matching with catheter tip cultures in our Microbiology Department.

Use of previously used resterilized catheters has not been previously reported. The high cost of the single use intra-parenchymal catheters restricts their usage especially in countries like India where the cost of treatment is born by the individual, and the majority of the patients are unable to afford it. There was no prolongation of hospital stay/incidence of meningitis/fever in the fresh catheters versus preused catheter group, and this was not significant on statistical analysis either. The fever observed in the neurosurgical patients could be caused by various reasons such as atelectasis of lungs or can be of central nervous system origin. Many patients have a posttrauma fever due to noninfective causes.[9,10] In our center during the period of this study, a CSF culture positivity was noted in 190 (3%) cases of 4943 positive samples of all patients admitted with various illness related to trauma, the remaining being positive in blood/treacheal and urine cultures.

The catheters were used in 1.44 ± 1.22 times (range: 1–4 times) in the present series. All catheters were tested for cultures at the time of removals. The cost of one intra-parenchymal catheter was brought down to half to two-thirds of its original cost by using it multiple times (range: 1–4 times). As there was no added costs born for any prolonged stay/higher antibiotics costs in the two groups, the use of preused catheters was found to be cost effective to the hospital without any safety or accuracy issues. The advantage of the intra-parenchymal catheters over the EVD is the reduced incidence of catheter colonization and meningitis.[8,11] With the reuse of these catheters the cost works out to about the same as with an EVD. We used antibiotics for the duration of the monitoring (in accordance with the hospital antibiotic policy). The incidence of meningitis was not affected by the duration of monitoring which is in concordance with the literature.[12] ICP catheter tip wash culture was positive in one patient. Multiple use of single use medical devices after reprocessing has been approved by FDA and is prevalent in other specialities mainly cardiology where angiography catheters and pacemakers are being reused with no increase in the rates of infection or change in efficacy however no such data is available for ICP catheters.[5,13,14] We do not recommend that catheters should be reused 2–3 times in all cases globally. However, the results of this preliminary study show that this practice of reusing intra-parenchymal ICP monitoring strain gauge catheters was found to be safe and cost effective and was not associated with significant zero drift either. This option of reusing intra-parenchymal ICP catheters can be considered by developing nation institutes with high workload of head injured patients where cost is a major deterrent in buying such catheters.

Conclusions

Reusage of ETO sterilized intra-parenchymal strain gauge ICP monitoring catheters was found to be safe, cost efficacious, and was not associated with any increased incidence of meningitis/

infections. With the considerable cost savings made possible by reuse of ICP catheters, implementation of this practice should be considered by health delivery systems especially more so in developing nations, provided that stringent methods of cleaning and sterilization are observed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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