Value Analysis Brief: CODMAN® MICROSENSOR® ICP Transducer for Intracranial Pressure Monitoring
Introduction

This value analysis brief provides analyses of intracranial pressure (ICP) monitoring systems on measures of clinical outcomes, accuracy, reliability, durability, and economic benefit, in the treatment of traumatic brain injury (TBI).

TBI is a complex injury that produces a broad spectrum of symptoms and potentially devastating disabilities.¹ ² Considerable treatment advances have occurred, contributing to a reduction in severe TBI mortality from 50% 30 years ago to less than 25% today.³ Outcome improvements result from interventions associated with greater understanding of how the neurological damage does not all occur at the moment of impact, but rather continues over the hours and days following the initial injury.⁴

Management protocols emphasize prompt resuscitation, early intubation, rapid transportation to a trauma care facility, early CT scanning, immediate evacuation of intracranial mass lesions, followed by meticulous management in an intensive care unit setting, with ICP monitoring.⁵ The main objectives of monitoring include rapid, detection of secondary injury and optimization of interventional strategies directed at secondary insults such as cerebral edema or ischemia.

The ICP monitoring technologies evaluated in this value analysis brief include:

- external ventricular drains (EVD) fluid coupled sensors
- micro strain gauge monitors (CODMAN MICROSENSOR Transducer (Codman, Raynham, MA, USA))
- fiber optic based interferometry sensors (i.e., the Camino® (Integra Neurosciences, Plainsboro, NJ, USA)).

Methods

Data were obtained via MEDLINE and Embase searches of peer-reviewed studies evaluating different monitoring technologies. We reviewed new evidence since The Brain Trauma Foundation (BTF) Technology Guidelines were published in 2007, using similar search criteria. Studies from April 2006 to October 5, 2011 were included. Additional literature searches using device and manufacturer names were used to capture studies not identified in the original search. Further, the reference lists of the studies reviewed for this brief were examined to find additional relevant studies.

Evidence-based Guidelines

The 2007 BTF Guidelines⁵ are the most widely accepted international guidelines for the management of TBI in adults. The guidelines are endorsed by the Joint Committees of Neurotrauma and Neurocritical Care of the American Academy of Neurosurgeons and the Congress of Neurosurgeons.

Numerous published guidelines recommend ICP monitoring, including the European Neurointensive Care and Emergency Medicine consensus on neurological monitoring,⁶ European Brain Injury Consortium (EBIC) guidelines,⁷ and Guidelines of the Italian Societies of Neurosurgeons and Intensivists.⁸

In 2004, the Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury in Infants, Children, and Adolescents were published, outlining similar recommendations for the pediatric population.

ICP monitoring has been the standard of care since 2007 in the US, when 77.4% of 413 designated trauma centers reported routine use of ICP monitoring.⁹ A 1996 survey of European centers found ICP monitoring was used in over 70% of patients.⁷
CODMAN MICROSENSOR Transducer versus External Ventricular Drain Sensors

BTF Guideline Findings
- The BTF Guideline review concluded that there was adequate evidence of accuracy with micro strain gauge monitors, but not with optical interferometry (fiber-optic) monitors, when compared to EVDs as the reference standard:
  - Readings from the CODMAN MICROSENSOR Transducer were within 2mmHg of the EVD sensor readings\textsuperscript{10,11}
  - Studies that monitored drift in the CODMAN MICROSENSOR Transducer showed consistently accurate readings when compared to EVD sensor readings.\textsuperscript{10,12}
  - All studies establishing accuracy and reliability of micro strain gauge monitors in the BTF guideline review used the CODMAN MICROSENSOR Transducer.

Evidence Since BTF Guideline
- A non-comparative study showed clinical outcomes with the CODMAN MICROSENSOR Transducer were favorable with no complications of infection or hemorrhage.\textsuperscript{13}
- A second study confirmed negligible drift over time with the CODMAN MICROSENSOR Transducer.\textsuperscript{14}
- Two comparative studies versus EVD sensors showed the CODMAN MICROSENSOR Transducer to be accurate and reliable.\textsuperscript{15,16}
  - One study showed the CODMAN MICROSENSOR Transducer detected crisis faster than EVD when continuously draining CSF, suggesting that a two-monitor system may be valuable in accomplishing goals.\textsuperscript{15}

Compared to EVD sensors, the CODMAN MICROSENSOR Transducer has a higher rate of more quickly detecting ICP crisis, thereby enabling more immediate treatment intervention.

Figure 1. ICP Crisis Detection by the CODMAN MICROSENSOR Monitor Compared to EVD Sensors.\textsuperscript{15}

75 ICP Spikes (ICP \geq 20 mmHg for \geq 5 min)
n=4 pediatric patients received continuous CSF diversion & underwent monitoring with both a CODMAN MICROSENSOR Monitor & EVD

- 55 (73\%) first detected by CODMAN MICROSENSOR Monitor
- 6 (8\%) detected simultaneously by CODMAN MICROSENSOR Monitor & EVD
- 14 (19\%) first detected by EVD Monitor
- 20 (26\%) later detected by EVD
- 35 (47\%) not detected by EVD
- 8 (11\%) later detected by CODMAN MICROSENSOR Monitor
- 6 (8\%) not detected by CODMAN MICROSENSOR Monitor

Compared to EVD sensors, the CODMAN MICROSENSOR Transducer has a higher rate of more quickly detecting ICP crisis, thereby enabling more immediate treatment intervention.
CODMAN MICROSENSOR Monitor versus Other Micro Strain Gauge Monitors and Optical Interferometry Monitors

BTF Guideline Findings

- BTF Guidelines determined there was adequate evidence to establish the accuracy and reliability of micro-strain gauge monitors, however, they found that "fiber-optic monitoring did not always correlate well with ventricular ICP":
  - Six drift studies with fiber-optic monitors did not have adequate results with respect to time drift. a,17,18,19,20,21,22

Evidence Since BTF Guideline

- Three studies evaluated micro strain gauge and optical interferometry monitors since the BTF Guideline review:
  - A study of Raumedic Neurovent-P reported that zero drift remained a concern with this catheter tip strain gauge technology.23
  - A prospective study of zero drift in the CODMAN MICROSENSOR System found median absolute drift to be 2.0 mmHg over 4 to 7 days.14
  - A study of the Camino optical interferometry monitor reported that the 10-day median drift measurement was 4 mmHg.24

The CODMAN MICROSENSOR Transducer has demonstrated equivalent or superior performance compared to other ICP probes on reliability over duration of use.

Table 1. Comparison of Features of the CODMAN MICROSENSOR Transducer to Integra Camino ICP Catheter*

<table>
<thead>
<tr>
<th>Features</th>
<th>CODMAN MICROSENSOR ICP Transducer</th>
<th>Integra Camino ICP Catheter</th>
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<tbody>
<tr>
<td>Technology</td>
<td>Piezoresistive strain gauge</td>
<td>Optical interferometry (fiber optic)</td>
</tr>
<tr>
<td>Susceptibility to bending or kinking</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Drift (mm Hg)</td>
<td>&lt;=5.0 per 7 days</td>
<td>0+/−2 first 24 hours (maximum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;=+/−1 per day over 5 days (typical)</td>
</tr>
<tr>
<td>Calibration method</td>
<td>Manual (button)</td>
<td>Manual (screw)</td>
</tr>
<tr>
<td>Suggested implantation time</td>
<td>Surgeon discretionb</td>
<td>5</td>
</tr>
<tr>
<td>Placement</td>
<td>Parenchymal, subdural, or ventricular</td>
<td>Parenchymal or ventricular</td>
</tr>
<tr>
<td>Probe depth markings</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fixation method</td>
<td>Bolt or tunnel</td>
<td>Bolt</td>
</tr>
</tbody>
</table>

* Data sources are Instructions for Use (IFU) Brochures26,27 and CODMAN Microsensor design history on file at Codman.

a Drift is the actual change in the measurement value when the same characteristic/parameter is measured under the same conditions at different points in time. Drift indicates theoretically how far from true value the measurement device may be. Normalized maximum drift (mm Hg) per 5 days are: 3.6 CODMAN; 5.0 Integra.
b The CODMAN IFU does not specify an implantation time for the CODMAN Microsensor. Duration of use for the CODMAN Micorsensor is at the discretion of the physician. Implantation time referenced in this brief has been taken from published literature for ICP probes. Sixteen days is the maximum duration reported by Koskinen, 28 days is the maximum duration for ICP monitoring reported by Vik. CODMAN has not evaluated implantation time.
Economic Implications

Figure 2. Cost of Transducers Per 100 Patients Across 1 to 28 Days of ICP Monitoring, Median 10 Days

Data and assumptions: A range of 1-28 days and a median of 10 days of ICP monitoring was used for this analysis. Range of costs are based on minimum and maximum numbers of transducers required for 50% of patients to be monitored from 1 to 10 days, plus the minimum and maximum numbers of transducers required for 50% of patients to be monitored from 11 to 28 days. From the published literature, 16 days is the maximum duration reported by Koskinen, 28 days is the maximum duration for ICP monitoring reported by Vik. Based on this information, the suggested implantation time referenced in product IFUs, as well as surgeon discretion, the CODMAN MICROSENSOR System could require 1 transducer per patient for days 1-10 and 1-2 transducers for days 11-28; Integra Camino could require 1-2 transducers/patient for days 1-10 and 3-6 transducers/patient for days 11-28. Uniform cost of $600/transducer assumed for all products. Camino example: minimum = $120k = $600 x ((1 trans x 50 pat) + (3 trans x 50 pat)); maximum = $240k = $600 x ((2 trans x 50 pat) + (6 trans x 50 pat)).

- Fewer transducers (1 to 2 versus 1 to 6) per patient are required with CODMAN MICROSENSOR system across the typical range of monitoring days (1 to 28 days).
- After a capital investment, switching 100 patients to CODMAN ICP Monitoring System could result in savings of $150k.
Discussion

The challenge to payers and healthcare providers is to maximize the net patient benefit obtained from healthcare expenditures. The rising costs of care delivery pose significant concerns to system viability, and thus improving outcomes while restricting costs is a primary concern of reform efforts around the world.

The current value analysis demonstrates that evidence supports the use of the CODMAN MICROSENSOR System as a reliable strategy for ICP monitoring in TBI. Several studies have demonstrated a high degree of accuracy in subdural, parenchymal, and intraventricular ICP monitoring with the CODMAN MICROSENSOR System. The CODMAN MICROSENSOR System may eliminate the need for system replacement due to drift. In that event, there would be no costly system replacement due to breakage, and without fluid lines as used in EVD pressure measurement, the time required in the maintenance and troubleshooting of a fluid system is eliminated.

Limitations of this analysis include:

1) Many of the studies on ICP monitoring have different patient inclusion criteria, lengths of follow-up, and endpoints.
2) Level II comparative and Level III case control evidence is confounded by the specifics of the technology used and how it is used.
3) ICP monitoring is only one contributor to patient outcomes. Treatment choice and timing are important factors.
4) The economic analysis only included the estimated cost of the transducers and capital equipment. Other medical costs and indirect costs (e.g., missed work and lost productivity) were not assessed in this evaluation.

More about the CODMAN ICP Monitoring System

The CODMAN MICROSENSOR ICP Monitoring System has been successfully and consistently used for nearly two decades with steady, increased adoption across applications.

The CODMAN MICROSENSOR ICP Monitoring System provides accurate measurements at the subdural, parenchymal or intraventricular levels and has inherent advantages over fiber-optic monitors, including cost.

ICP information is relayed electronically rather than through a hydrostatic column or fiber-optics.

The ICP EXPRESS® is a digital ICP monitor that also serves as an interface between the CODMAN MICROSENSOR ICP Transducer and patient monitors.

The one-touch button operation of the ICP monitor permits simple equipment setup for monitoring ICP.

ICP EXPRESS provides a continuous digital display of systolic, diastolic and mean ICP.

New features include depth markings and tightening of specifications.
References


