Achieving rigour and relevance in an HTA of double balloon endoscopy

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CADTH Invitational
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Overview

- Technology Description
- Methodological challenges
- Informational needs of policy makers
- Balancing rigor and relevance
Hironori Yamamoto 2001

- Proof of concept paper
- Small case series with 3 patients
- Primary piece of evidence is an image like this showing an endoscope completely traversing the small intestine
Double Balloon Enteroscopy
Media is the message...
Accolades for DBE

Small bowel endoscopy: have we conquered the final frontier? Am J Gastroenterol. 2007 Mar

Double-balloon enteroscopy and EUS: is there anything now we can't see? Gastrointest Endosc. 2007 Mar


Double-balloon enteroscopy: the new gold standard for small-bowel imaging? Gastrointest Endosc. 2005
Challenge 1

Highest level of available evidence

- uncontrolled case series
  - Prospective
  - Consecutive
  - Follow-up
  - (Large >100 cases)
Heirarchy of evidence

1. Systematic reviews and meta-analyses
2. Randomised controlled trials
3. Cohort studies
4. Case-control studies
5. Case series
6. Case reports
7. Expert opinion
8. Anecdotal
Cochrane Review

Ex. Endoscopic mucosal resection for early gastric cancer

- Randomized or quasi – randomized
- Defined diagnosis – tumors meeting internationally accepted criteria
- Defined comparator - gastrectomy
- Defined outcomes – survival, recurrence, QoL
More research needed?

Undoubtedly however...

Little demand from stakeholders

HTA consumers vs. thesis committees unsatisfied with this standard conclusion
Rigor versus Relevance

Cochrane approach requires a narrow focus to establish causal relationships that are generalizable.

Policy makers need to know how it is likely to be used in local practice and what the impact on health and resources.
Social and System Demographics

- Relevant diagnoses
  - Prevalence/incidence trends

- Population dynamics
  - Age/gender structure
  - Ethnic/cultural mix
  - Education, Income

- Patterns of illness
  - Description, natural Hx, psychosocial, economic, lifestyle effects

- Reduction in burden of illness/QoL

- Treatment variation
Social and System Demographics

Patterns of Care
- Hx and development of procedures
- Options/ standards
- Affect on population characteristics on access

System capacity to provide care
- Practitioners, support staff
- Patient/practitioner ratios
- Affect human resources on access
- Required system supports
Technology
Effects & Effectiveness

Safety
- Evidence of benefit, effectiveness
- Outcome measures
- Benefit to risk ratio

Condition etiology
- Standard algorithm

Difference compared to usual care

Diagnostic test parameters

Follow-up care

Outcome by population characteristics

Regulatory approval

Professional standards

Developments on the horizon
Fiscal and Economic

- Substitute or add on?
- Demand – contextualized by condition(s), in comparison to alternatives,
- Indicators for use

- Unit cost estimates
  - Physician billing, operational costs, capital costs for procedure and services
- Cost of services avoided
- Potential for cost transfer
- Cost management
Challenge 2

Heterogeneity

- Indications
- Diagnostic and therapeutic uses
- Conditions of interest
- Final diagnoses
- Outcome measures
Non-specific signs and symptoms

- gastrointestinal bleeding (like melena or hematochezia)
- abdominal pain
- chronic diarrhoea
- signs of obstruction
- laboratory indicators of malabsorption
Heterogeneity: Conditions of Interest

- Angiodysplasias
- Primary neoplasias/Metastasis
- Polyposis syndromes
- Meckel diverticulum
- Medication-induced mucosal lesions (NSAIDs, KCl)
- Portal hypertensive intestinal vasculopathy
- Crohn’s disease
- Aortoenteric fistula
- Hemosuccus pancreaticus
- Hemobilia
Heterogeneity: Final Diagnoses

32 distinct final diagnoses (Zhong 2007)
Diagnostic uses

- Visual inspection
- Biopsy
- Pre-surgical tattooing
Therapeutic Maneuvers

- Coagulating bleeds
- Removing polyps
- Releasing strictures
- Resecting lesions
- Retrieving foreign objects
Outcomes

- Mortality
- Transfusion rates
- Symptoms
- Bleeding indexes
Comparators

- Video capsule endoscopy
- Intra-operative endoscopy
Retrieving Video Capsules
Clinical Pathway for DBE

Figure from MSC EBE Review 2006 (54, p. 7) Used with permission
Highly select group

- Filter – not diagnoses by conventional endoscopy (via colon or esophagus/stomach), laboratory or other imaging, and increasingly video capsule

- 322 per year

- Move towards adopting a standard of DBE first for acute obscure bleeds

- Challenges for identifying in historical administrative datasets
Broad focus

The full capabilities of DBE are likely to be used if DBE were to become a publicly funded service in Alberta. A broad focus encompassing nineteen interrelated research questions was therefore used in an HTA strategy undertaken to review all available evidence on the social, fiscal and economic impact of DBE.
Findings: Indications

- 59% Bleeding
- 17% Structural or tumors
- 14% Chronic pain/diarrhea
- 6% Crohn’s / Celiac disease Evaluation
- 4% Other
- 17% Other
Findings: Complications

1% overall major
Post polypectomy bleeding rate 10.8%
Survey 3.3%

Minor (requiring up to 3 days of hospitalization)
Moderate (requiring 3±10 days of hospitalization)
Major (requiring > 10 days of hospitalization, and/or an endoscopic, radiological or surgical intervention, and/or contributing to the death of the patient)
Findings

97% reported success rate of DBE-enabled therapeutic interventions

1 study health outcomes (decreased symptoms)

Diagnostic yeild 75% (range 52-93%)

Classic test parameters unavailable

Comparable to VCE with additional capability to biopsy and treat
Findings

- **Technical failure:** 3.3%
- **Equipment failure:** 0.8%
- **Procedure time:** $73.5 \pm 25$ (range 25-131) minutes

- **Cost estimate:**
  - $2,181 per procedure without therapy
  - $2,715 with therapy

- **Versus inpatient costs of treating GI bleeds**

- **Social, legal or ethical issues** not contentious
## Unit Costs in Canada

<table>
<thead>
<tr>
<th>Item</th>
<th>Estimate</th>
<th>Source of estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase price</td>
<td>$55,750</td>
<td>Carsen Medical Inc, Canada distributor of Fujinon DBE technology</td>
</tr>
<tr>
<td>- DBE enteroscope (EN-450T5)</td>
<td>$26,750</td>
<td></td>
</tr>
<tr>
<td>- Balloon Pump Controller (PB-20)</td>
<td>$82,500</td>
<td></td>
</tr>
<tr>
<td>Equipment essential for DBE Subtotal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non essential items with research and other uses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Processor (EPX-4400)</td>
<td>$38,750</td>
<td>Carsen Medical Inc estimate over 5 years with lower estimated costs in first and second years of operation</td>
</tr>
<tr>
<td>- Cart (PC-30)</td>
<td>$5,750</td>
<td></td>
</tr>
<tr>
<td>- Monitor (19” Radiance monitor)</td>
<td>$5,400</td>
<td></td>
</tr>
<tr>
<td>GST Total</td>
<td>$132,400</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$7,944</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$140,344</td>
<td></td>
</tr>
<tr>
<td>Estimated clinical life of equipment</td>
<td>5 years</td>
<td>Carsen Medical Inc</td>
</tr>
<tr>
<td>Annual equivalent cost of equipment</td>
<td>$ 30,872</td>
<td>Annuity at 5% p.a. for 5 years</td>
</tr>
<tr>
<td>Annual maintenance costs</td>
<td>$2,500</td>
<td>Carsen Medical Inc estimate over 5 years with lower estimated costs in first and second years of operation</td>
</tr>
<tr>
<td>Total major capital equipment cost per annum</td>
<td>$33,372</td>
<td></td>
</tr>
<tr>
<td>Estimated annual volume of procedures</td>
<td>50 plus</td>
<td>Alberta expert advisor estimate on annual use per DBE site</td>
</tr>
<tr>
<td>Estimated cost per procedure for equipment and maintenance</td>
<td>$667</td>
<td></td>
</tr>
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## Total cost per unit of DBE equipment, specialist and day facility costs

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<tbody>
<tr>
<td>Equipment cost: capital and maintenance per procedure</td>
<td>$667</td>
<td>(above)</td>
</tr>
<tr>
<td>Specialist fees</td>
<td>$633.60 (including biopsy) ($989.44 with therapy)</td>
<td>Clinical experts concur that the procedural time for DBE is approximately four times that for colonoscopy and that therefore it would be reasonable to multiply the fee for colonoscopy by four. AHCIP fee code 01.22</td>
</tr>
<tr>
<td>Cost associated disposables</td>
<td>$344.5</td>
<td>Carsen Med Inc, Canada Overtube TS-13140 Carsen Med Inc, Canada Balloon for enteroscope BS-2 (10 balloons per package with 1 used per procedure)</td>
</tr>
<tr>
<td>Cost of day hospital facility services</td>
<td>$496</td>
<td>GI endoscopy Low: (highest cost) based on relative resource use: p 282 Health Costing 2005.</td>
</tr>
</tbody>
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