# Save and Safe in Therapeutic Endoscopy

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# Scope

- Health economics evaluation
- Safe and save: disease management
  - Stenting in hilar cholangiocarcinoma
  - Dilation of benign esophageal stricture

# Save & Safe

- Save - Cost
- Safe - Health Outcome
  - Efficacy & Complication
  - Utility
  - Money

"ECONOMICS EVALUATION"

# Characteristics of Health Care Evaluation

<table>
<tr><td></td><td colspan="4">Both costs and consequences examined?</td></tr>
<tr><td rowspan="3">Comparison of two or more alternative?</td><td rowspan="2">No</td><td colspan="2">No</td><td>Yes</td></tr>
<tr><td>Examine only consequence</td><td>Examine only costs</td><td rowspan="2">Cost outcome description</td></tr>
<tr><td>Outcome description</td><td>Cost description</td></tr>
<tr><td>Yes</td><td>Efficacy / effectiveness evaluation</td><td>Cost analysis</td><td>Full economic evaluation<br>-CEA<br>-CUA<br>-CBA</td></tr>
</table>

Drummond MF. Methods for the economic evaluation of health care program 2005

# Economic Evaluation

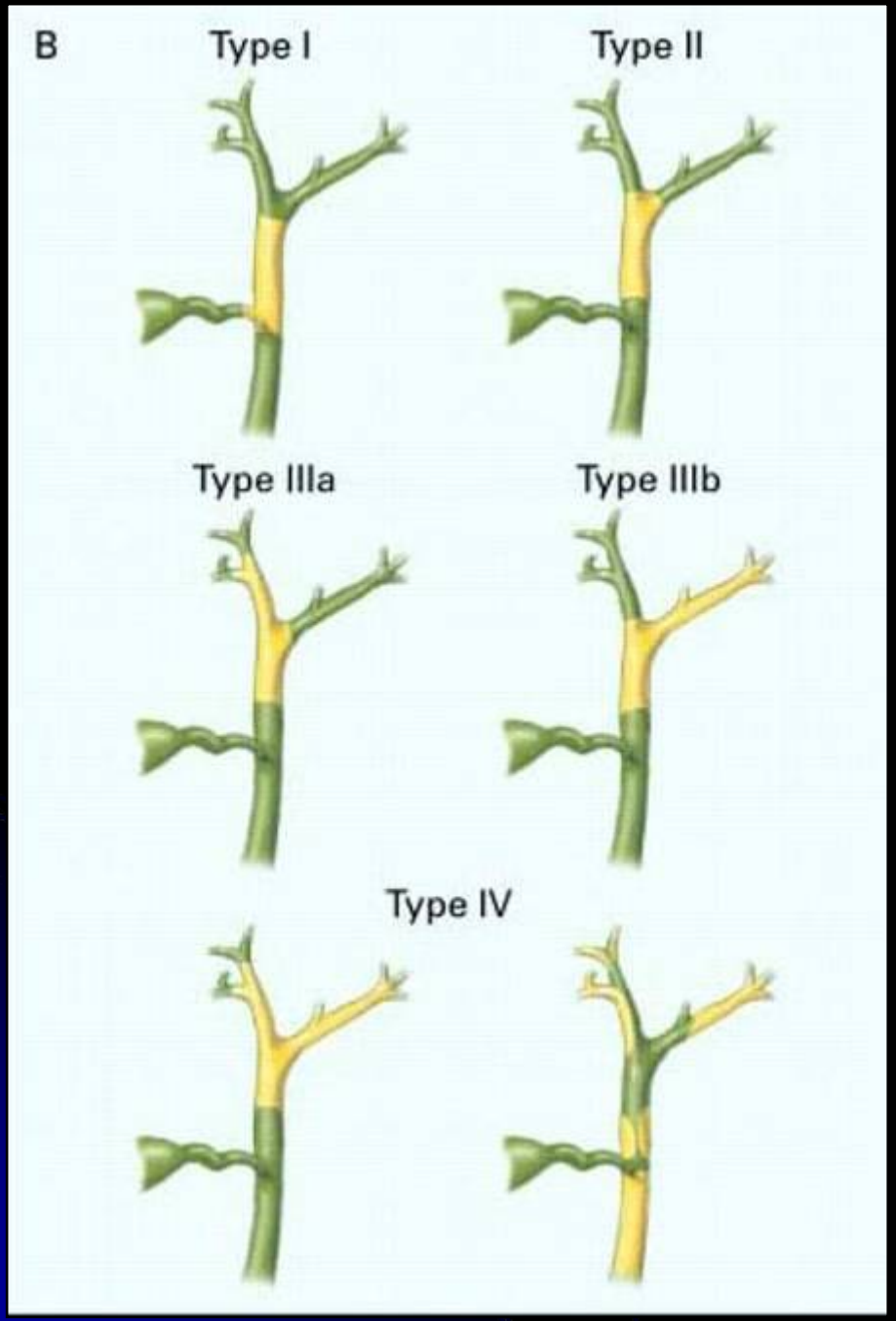
- Cost minimization analysis (CMA)
  - Consequence or outcome of programs are equivalent.
  - Cost comparison
- Cost effectiveness analysis (CEA)
  - Clinical outcome in natural unit e.g. mmHg, case detected, procedure prevented.
  - Can not compare between different programs

# Economic Evaluation

- Cost utility analysis (CUA)
  - Outcome in common unit
    - QALY = Quality-Adjusted Life Year
    - DALY = Disability-Adjusted Live Year
    - HYE = Health-Years Equivalent
  - Useful technique to compare between different programs
- Cost benefit analysis (CBA)
  - Provide absolute benefit of programs
  - Compare cost and benefit in money terms.

# Cholangiocarcinoma (CCA)

- Most common malignant liver tumor in North-Eastern and Northern Thailand
- Liver fluke: *Opisthorchis viverrini.*
- Natural History
  - Slow growing tumor
  - Local invasion
  - Lymphatic spreading

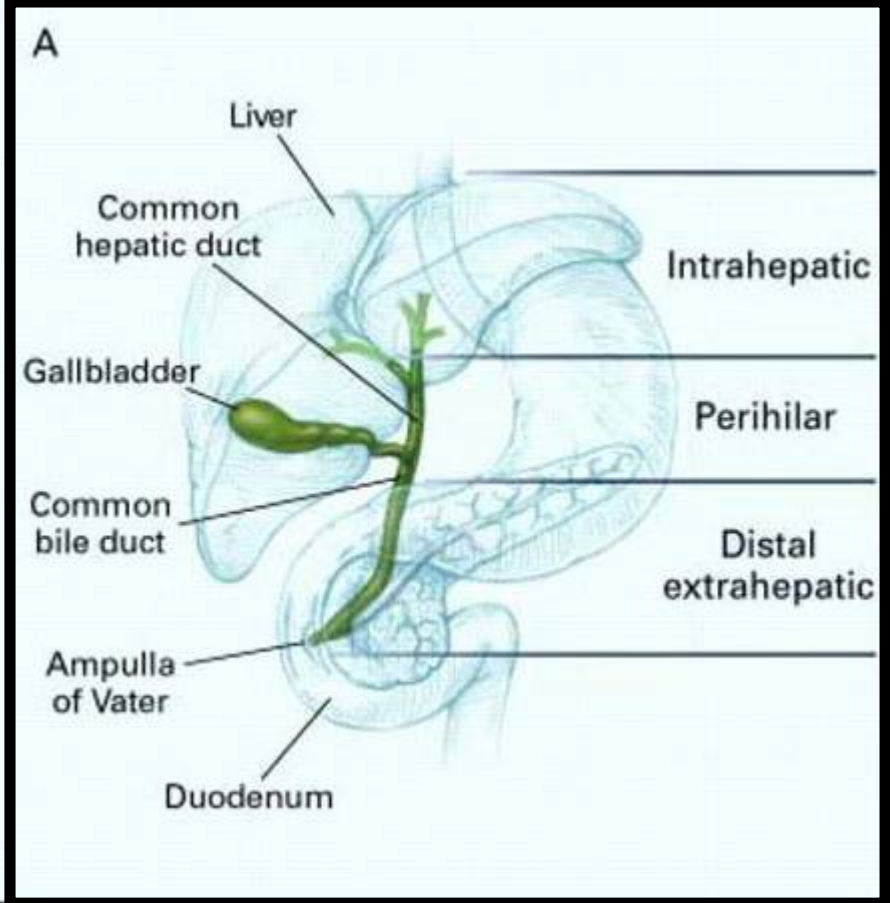



**Intrahepatic tumor (15%)**

**Perihilar tumor (60-70%)**

**Bismuth classification I-IV**

**Extrahepatic distal tumor(20%)**



# Resectability

- **Memorial Sloan-Kettering T stage**
  - Correlate with resectibility and survival
  - T1: -Unilateral extension to second-order biliary radicals
  - T2: -T1 + ipsilateral PV inv. ± ipsilateral hepatic lobar atrophy
  - T3: -Bilateral extension to second-order biliary radical
    -Unilateral extension to second-order biliary radical with contralateral PV or HA involvement or hepatic lobar atrophy
    -Main or bilateral PV involvement
- AJCCS
  - $N_1a$
    - hepatic, cystic, common duct and hepatoduodenal ligament LN
  - $N_1b$
    - Distant LN
  - M0, M1

# Treatment Options

- Curative surgery
- Palliative treatment in unresectable tumor
  - Improved survival
    - Photodynamic therapy
    - Brachytherapy
  - Not improved survival
    - ERCP with stent
    - PTBD
    - Bypass surgery

# Stenting

- Aim of palliative treatment
  - Symptom resolution
  - Improvement in QOL
  - Cost effectiveness

- Full economics evaluation
  - No evidence in Hilar CCA
  - Few papers in Malignant CBD obstruction

# Stenting

- CT or MRCP is necessary*,**
  - To guide stent placement into the largest intercommunication group of IHD
  - Reduced post ERCP related cholangitis
- 25% of the liver needs to be adequately drained in order to relieve jaundice***
- Save  &safe?
  - Unilateral or Bilateral stent insertion?
  - Plastic or Metallic stent?

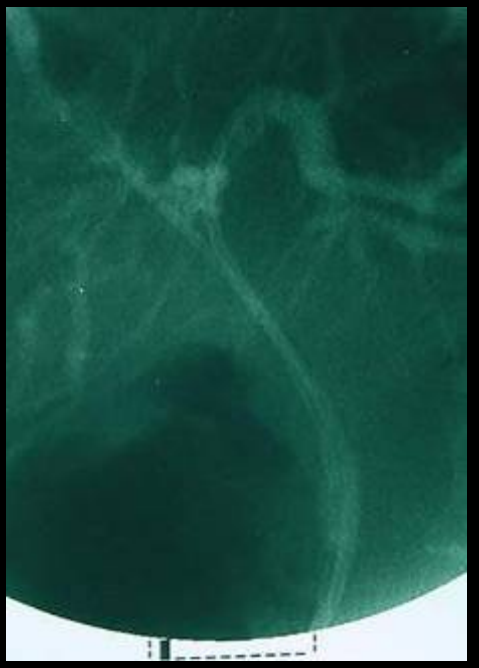
*Freeman ML. Gastrointest Endosc 2003

**Hintze RE. Gastrointest Endosc 2001

***Dowsett JF.  Gastroenterology 1989

# Stenting

- Unilateral vs. Bilateral stenting
  - RCT 157 hilar obstruction
    - CCA 57.3%
    - GB cancer 19.7%
    - Periportal LN metastasis 25%
  - Bismuth classification
    - I =31.2%
    - II & III =68.8%
  - 10F plastic stent



De Palma GD. Gastrointest Endosc 2001

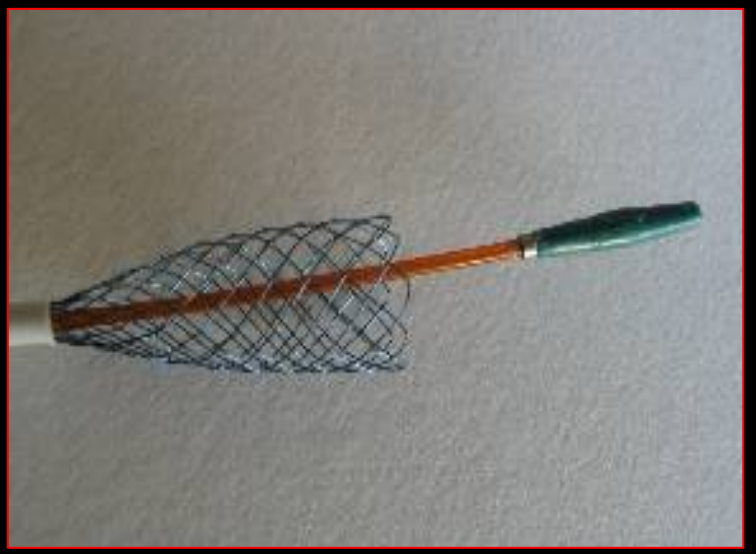
# Stenting

- ITT analysis
  - Successful stent insertion
    - 88.6% VS. 76.9%; p=0.041
  - Successful drainage
    - 81.0% VS 73.0%;p=0.049
  - Less cholangitis in unilaterally stent group
    - 8.8% VS. 16.6%; p=0.013
    - Minimal injection of contrast
    - Reduced duration of catheter manipulation
    - Avoidance of overfilling undrained ducts with contrast
  - Similar median survival
    - 140 VS 142 days

De Palma GD. Gastrointest Endosc 2001

# Metallic or Plastic stent

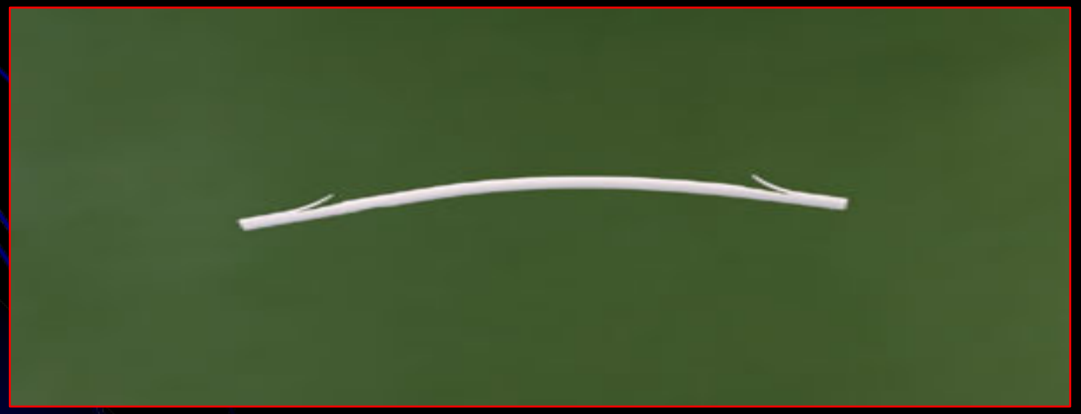
- Metallic stent
  - Open-mesh: drainage of side branch
  - Larger diameter
  - Longer patency (~3-9 months)
  - Expensive



# Metallic or Plastic stent

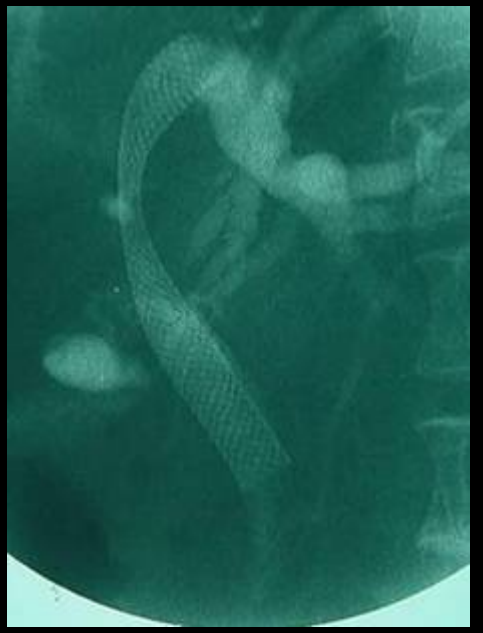
- Plastic stent
  - Lower initial cost
  - High occlusion rate:  3-4 months.
    - subsequent costs for stent exchange and complications

- In patients with hilar CCA, which one is better in terms of adequacy of drainage or cost-effectiveness remains undefined.



# Metallic or Plastic stent

- Small RCT*
  - 20 patients with type II-IV hilar obstruction
  - No. of re-interventions were sig. higher in plastic stent gr. (2.4+/-2.6 VS 0.4+/-0.5)
  - Hospitalization for Rx of complication was sig. higher in plastic stent gr.
  - Long term stent failure (>30days) was higher in plastic stent gr. (50% VS. 18.2%; not sig.)
- Survival difference?



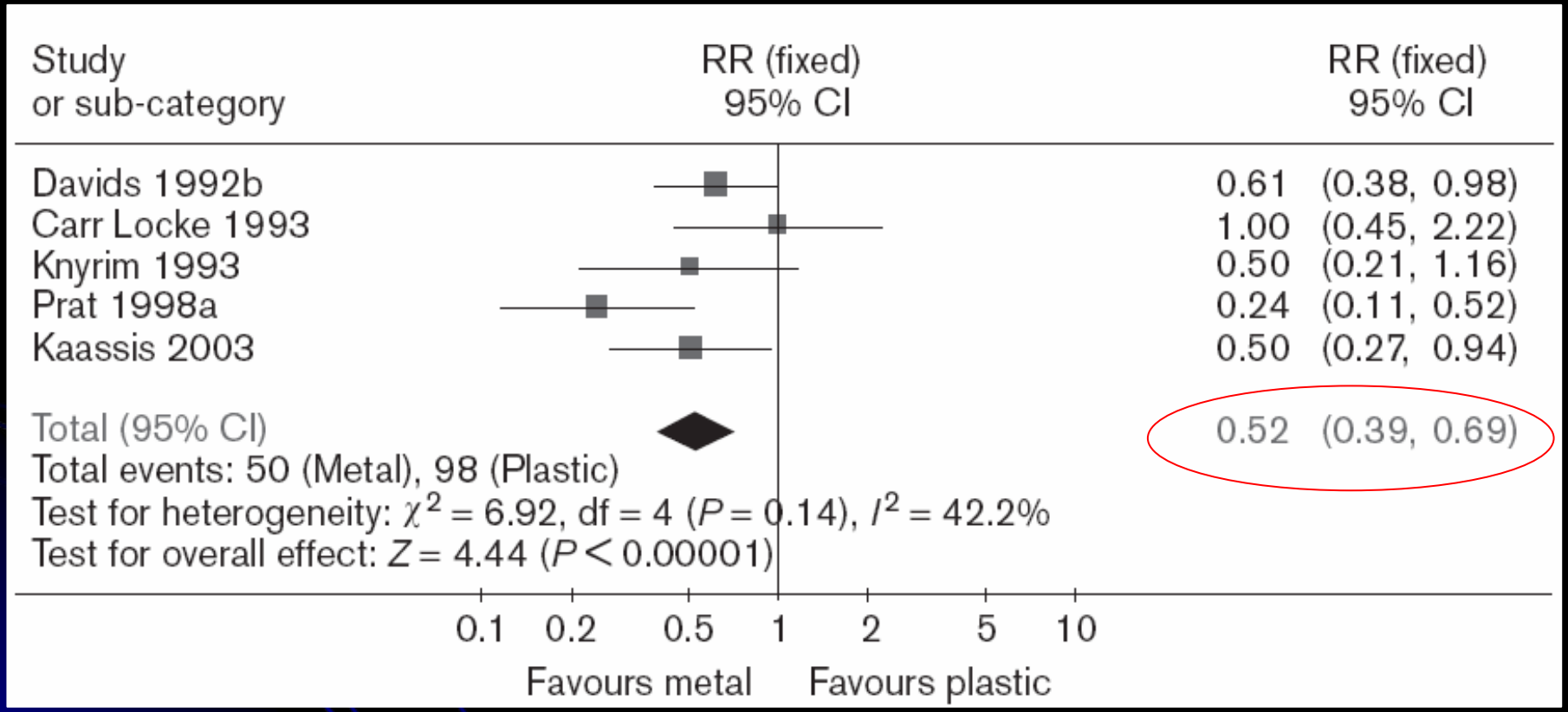
*Wagner HJ. Endoscopy 1993

# Systemic Review and Meta-Analysis

- Metal VS. Plastic stent
  - 7 studies
  - 724 patients
  - Malignant biliary tract obstruction
    - 52-89% of cases are pancreatic cancer patients.
    - 2.5-21% are CCA but most of them are CBD lesions.

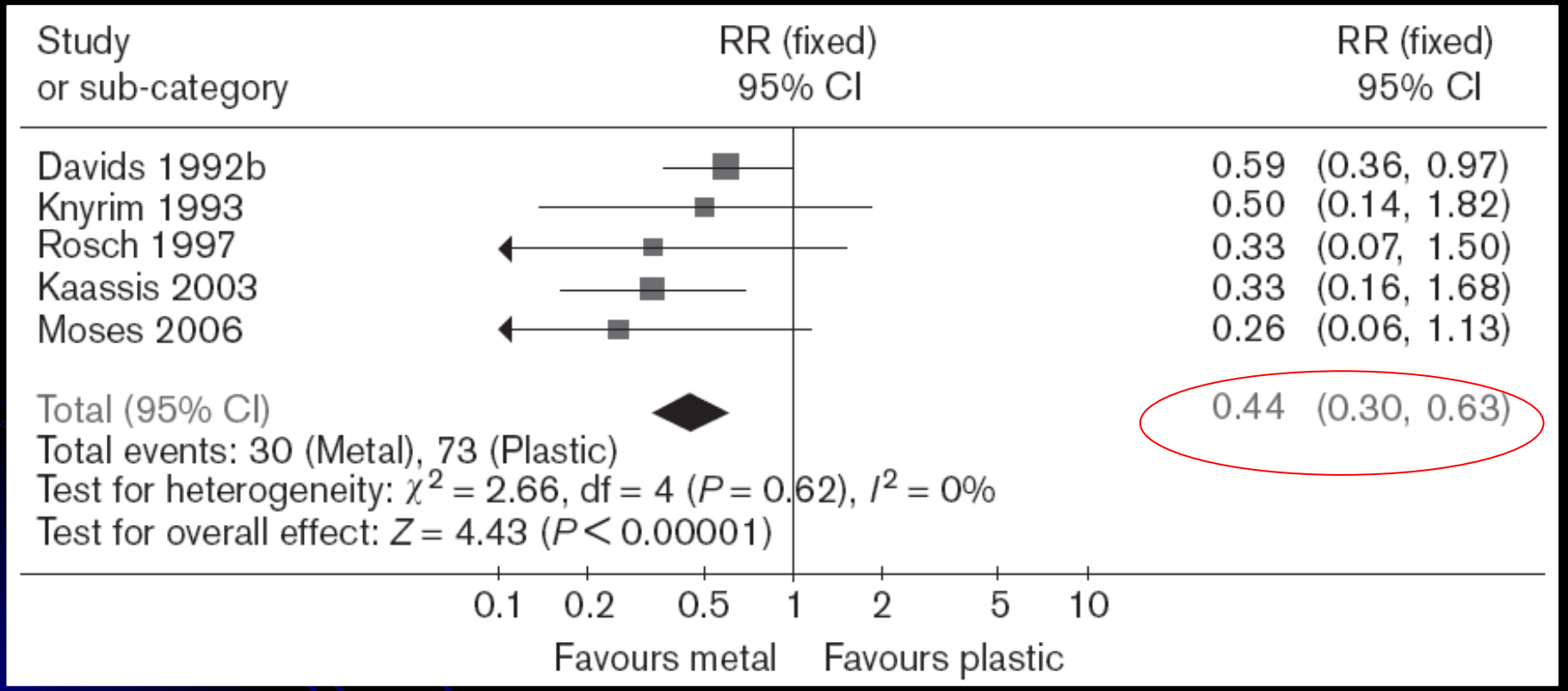
Kaassis M. Gastrointest Endosc 2003

# RR of recurrent occlusion prior to death / end of study



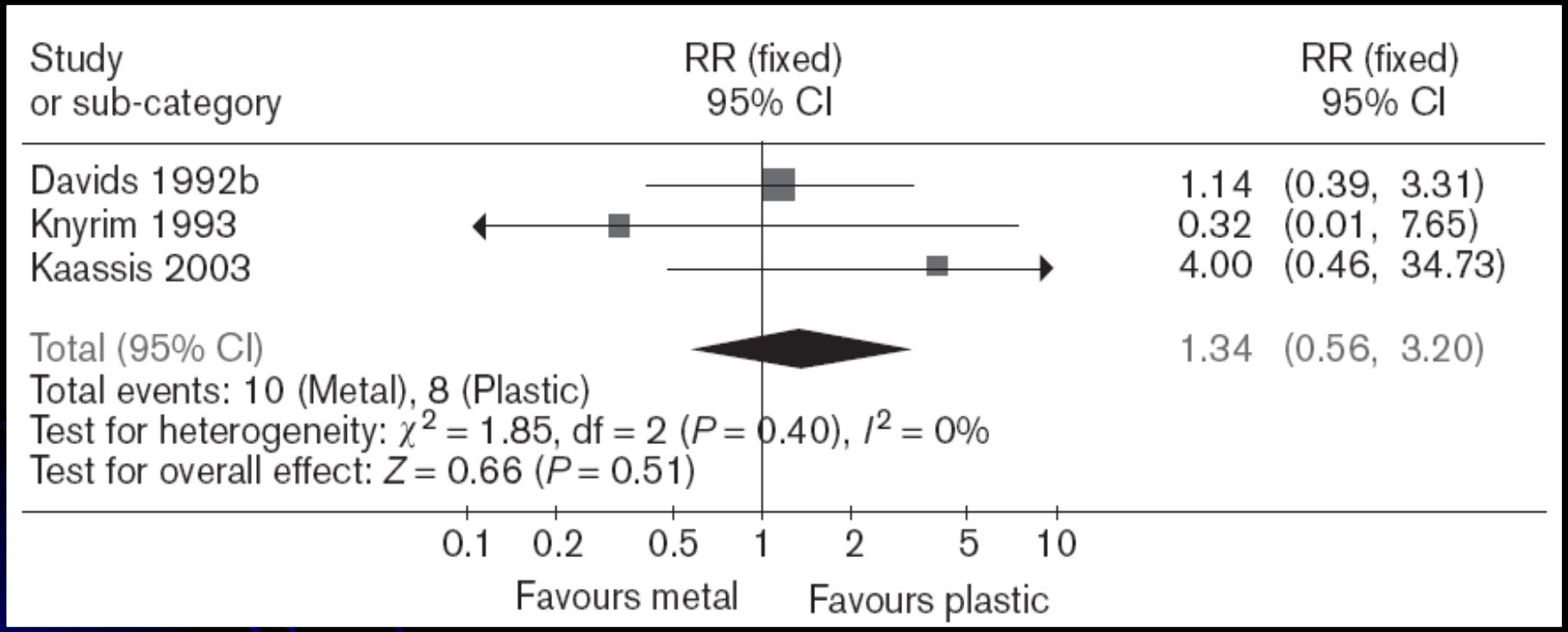

Kaassis M. Gastrointest Endosc 2003

# RR of stent occlusion at 4 months



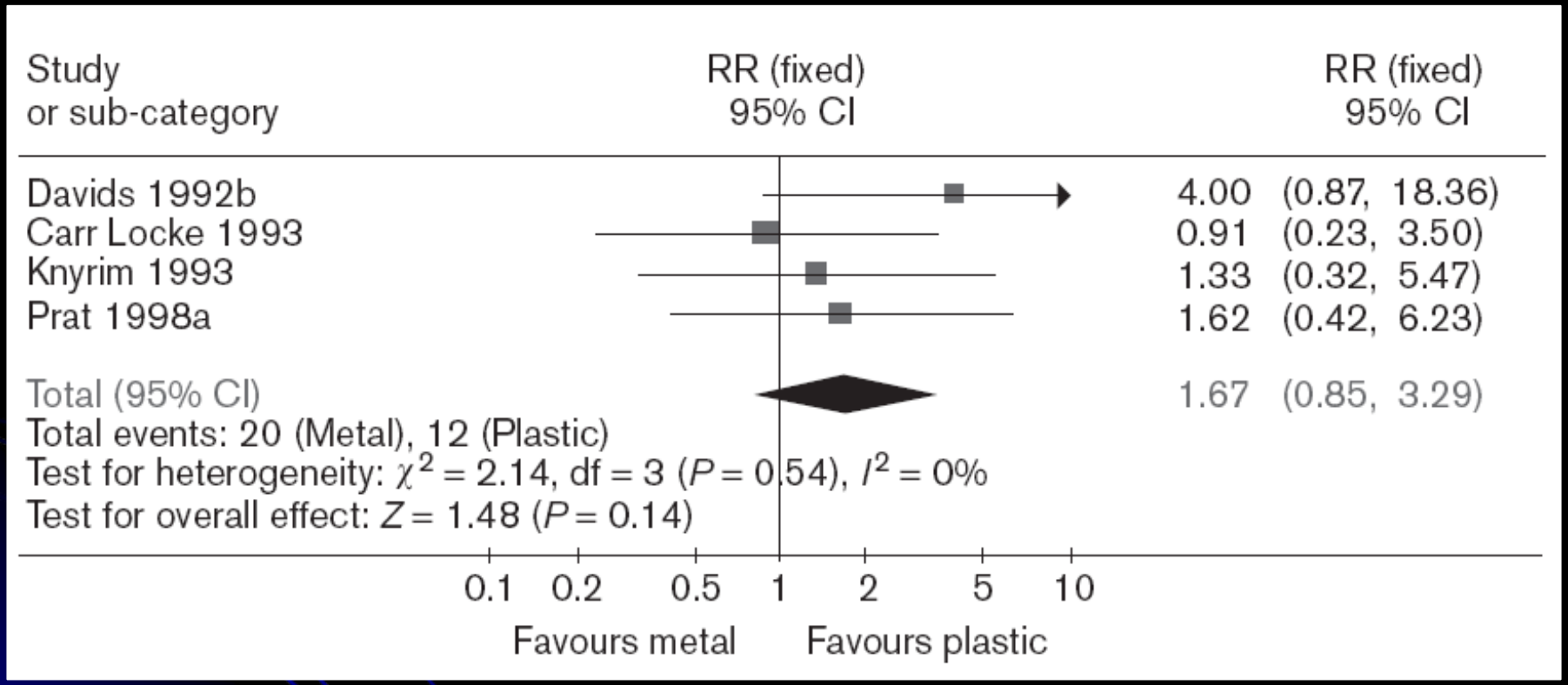

Kaassis M. Gastrointest Endosc 2003

# RR of complication post stent insertion




Kaassis M. Gastrointest Endosc 2003

# RR of 30 day mortality post stent insertion




Kaassis M. Gastrointest Endosc 2003

# Systemic Review and Meta-Analysis

- Cost-effectiveness in 4 studies
  - ICER for prevented 1 ERCP procudure = 1,682-2,722 US dollars

- No difference in technical failure & therapeutic failure

Kaassis M. Gastrointest Endosc 2003

# Benign Esophageal Stricture

- Common presenting: solid food dysphagia
  - Usually occurs when diameter ≤13 mm.

- Causes
  - Caustic injury
  - Peptic stricture
  - Radiation injury
  - Pill-induced esophagitis
  - Rings and webs

# Benign Esophageal Stricture

- Classification
  - Simple strictures
    - Symmetric or concentric with a diameter of ≥12 mm
  - Complex strictures have one or more of the following features:
    - Asymmetry
    - Diameter ≤12 mm
    - Inability to pass an endoscope.

- Indication for dilation of benign strictures
  - Dysphagia

# Type of Esophageal Dilators

- Mercury / tungsten filled bougies
  - Maloney dilator
- Wire guided bougies
  - Savary bougies
  - American Endoscopy bougies
  - Celestin (step wise diameter increase)
- Through the scope (TTS) balloon dilator

# Mercury / Tungsten Filled Bougies

- Sitting or left lateral decubitus position
- Initial dilator based on the estimated stricture diameter
- Rule of “Three” & repeat in 1-3 weeks
- Save
  - Reusable
  - Do not need guidewire and endoscopy
  - Use fluoroscopy liberally
    - Narrow stricture
    - Large hiatal hernia
- Safe
  - Useful in case of simple, straight strictures
  - Risk of perforation higher than wire guided bougies/TTS balloon dilation in complex stricture*

*Hernandez LV. Gastrointest Endosc 2000

# Wire-guided Bougies

- Save
  - Reusable dilators & guide wire
  - Variation in techniques
    - Fluoroscopy
    - Endoscopy
- Safe
  - GW is directed through stricture
  - Endoscopic or fluoroscopic guidance

# Wire-guided Bougies

- Variation in techniques
  - Standard technique
    - GW was passed though stricture under endoscopic guidence
    - Endoscope was removed
    - Dilators was passed through stricture over wire and under fluoroscopic control
  - Without fluoroscopy*
    - Dilators was passed through stricture over Savary-Gilliard GW / hydrophilic GW
    - Fluoroscopy was not used to monitor dilator passage

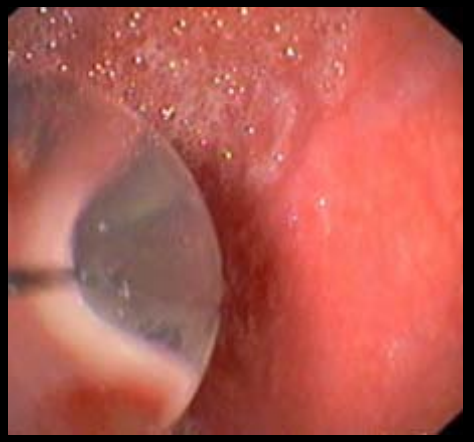
*Wang YG. World J Gastroenterol 2002

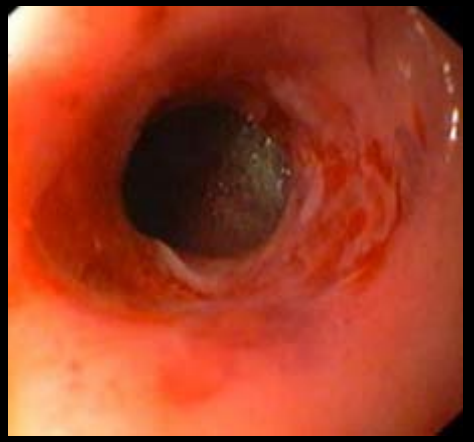
# Wire-guided Bougies

- Variation in techniques
  - Fluoroscopic control without endoscopy
    - Hydrophilic GW was passed into esophagus accompany with smallest (5mm.) Savary dilator
    - GW was negotiated through stricture under fluoroscopy
    - Dilation was performed over hydrophilic wire under fluoroscopic control

# TTS Balloon Dilator

- Conventional & Controlled radial expansion (CRE)
  - Three different inflation steps → graded dilation
- ?Save
  - Single use / reused for a few times
  - Expensive
- Safe
  - Soft tip and passed under direct vision / wire guided





# TTS Balloon Dilator

- No need to follow rule of “Three”
- Factors associated with a poor response to balloon dilation*
  - Length of >8 cm
  - Small predilation luminal diameter
- Long-term benefits of dilation appear greatest when a luminal diameter of >12 mm is achieved**

*Saeed ZA Gastrointest Endosc 1997
**Said A  Am J Gastroenterol 2003

# Wire-guided Bougies VS. TTS Balloon

- Two randomized controlled trials
  - Equally effective and safe in benign lower esophageal strictures*
  - Balloon dilation is better for **
    - Prevention of recurrence at 2nd year,
    - Fewer sessions
    - Less discomfort
- No economics study

*Scolapio JS. Gastrointest Endosc 1999

**Saeed ZA. Gastrointest Endosc 1995

# Conclusions

- Stenting in hilar CCA
  - Plastic or Metal stent
    - The patients' overall health
    - Expected length of survival
  - Uni- or Bilateral stent
    - Unilateral drainage is enough
    - Drain all opacified lobe
  - Careful imaging prior to ERCP with targeted drainage of specific segments.

# Conclusions

- Dilation of benign esophageal stricture
  - Mercury / Tungsten Filled Bougies in simple straight stricture is the cheapeast method
  - Wire-guide bougies tend to be cheaper than TTS balloon dilations with the same efficacy and complication but more discomfort
  - There are variations in techniques of wire-guide bougies dilation
    - Depend on available instruments and experience of endoscopist.

# ขอบคุณครับ

# Technique of Wire-Guided Bougies

- Most series report dilation upto 40-60Fr
  - Good relief of symptoms
  - Low complication rate
- Generally assumed that little benefit with dilation >50-54 Fr (42 Fr may be enough in asian people)
- Rule of threes
  - Not more than 3 sizes above significant resistance
  - Frequency: weekly or 2-3 session in 10 days

# Technique of TTS balloon dilation

- Reported series use balloons that larger than rule of threes
  - Inflation of a single large diameter dilator (>15 mm) or incremental dilation of greater than 3 mm may be safe*
- For larger sizes it may be safer to perform dilation in two session

*Kozarek RA. J Clin Gastroenterol 1995