Natural orifice approach to MR-guided ultrasonic tumor ablation

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SCIT Seminar, October 2, 2013
History of Surgery

• The whole historic evolution is largely a story of decreasing invasiveness of effective procedures

• The overall goal has been decreasing invasiveness of effective surgical treatments, in order to minimize the possibility of infection, time for tissue healing and deleterious side effects
History of Surgery

- Open Surgery exclusively
  - Extensive tissue damage
  - High incidence of infection/complication

- Laparoscopic Approaches
  - More recently: robotic assistance

- Two relatively new approaches:
  - Natural orifice surgery
  - External HIFU treatment of tumors
What is Natural Orifice Surgery?

• Surgery that exploits access to pathologic processes in the body via a natural orifice route rather than incisions.

• Routes include:
  ▪ Transvaginal
  ▪ Transrectal
  ▪ Upper GI- transgastric/small bowel
  ▪ Transurethral
Welcome to NOSCAR.org

NOSCAR - A joint initiative supported by the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

It is unique in one’s career in medicine to see a true paradigm shift that significantly changes patient management. This generation experienced such a paradigm shift with the introduction and development of laparoscopic surgery. It is possible that we are on the verge of another paradigm shift – Natural Orifice Translumenal Endoscopic Surgery (NOTES)®.
'Natural orifice' surgery has tongues wagging

By Rita Rubin, USA TODAY

Lynn Masterson hurt in a most unusual place after gallbladder surgery June 16.

"I had actually had more pain and decreased mobility with my tongue," says Masterson, 47, a radio station traffic reporter.

That's because her surgeon pulled her gallbladder out through her mouth.

She was Lee Swanstrom's third through-the-mouth patient. Swanstrom, of the Oregon Clinic, performs Portland's Legacy Good Samaritan Hospital.

Friends and family were shocked to learn Masterson's gallbladder took from her body.

Masterson joked that he had wondered why her breath smelled so bad after surgery.

The thought of having the gallbladder extracted through the mouth or, in women, the vagina, is enough to make most people gag.
How does Focused Ultrasound Work?

Ultrasound energy is focused at a point deep within the body.

Ultrasound is absorbed as heat.

Intervening tissue is unaffected.

A single lesion can be made very rapidly: several seconds.
Heating for tumor ablation

Hyperthermia:

- Frequently used in conjunction with XRT, may be complementary, temperatures raised for at least several minutes to ~41 to 45 Degrees C.

Focused Ultrasound Heating:

- Much higher temperatures generated for seconds, typically to the range of 50 to 90 Degrees C.
- Generally causes very rapid local tissue ablation via coagulation of tissue proteins
MRgFUS Hardware
Extracorporeal HIFU Route
Types of FUS Systems

Extracorporeal

Intercavitary
MRgFUS in Prostate

~41,000 Treated with US-guided FUS (FUS Foundation)
- Japan and Europe

Transrectal

Transurethral

Napoli, A
European Symposium on MRgFUS Therapy, 2011

Chopra R, Int J Hyperthermia 2010
Methods: Transurethral applicators

- Placement Balloon
- Cooling Balloon
- Enclosing Transducers
- Rectal Coil
- Applicator with cooling balloon
Results: Planar transurethral applicator

-8-6 mm.  Mid-Prostate  +6 mm.

First Heating

Applicator Rotation

Second Heating

Red overlay indicates temperature of at least 52 Deg. C, Orange 47 Deg. C
Results: Planar transurethral applicator

Gad-enhanced T1-weighted MRI

Corresponding TTC-stained section

Axial sections 6 mm. Cranial from mid-prostate

Thermal maps during maximal heating
Anatomy of BPH

Normal

BPH

PROSTATE

BLADDER

URETHRA

Hypertrophied detrusor muscle

Obstructed urinary flow

Prevalence of BPH Increases With Age

Age
51-60: 42%
61-70: 71%
71-80: 82%
81-90: 88%

(N=1,075)

BPH- Clinical Importance- Rx

- Medical Treatments
- Minimally-invasive treatments RFA, TUMT, transrectal HIFU
- Surgery: 95,340 surgical procedures for BPH in US (1998)\(^1\), compared to <36,000 for prostate Ca (2001)\(^2\)

\(^1\) J Urol 2008;179:S75-S80 \(^2\) Urol Dis in America, 2007
Schematic transverse section of normal prostate

- Urethra
- Transition Zone
- Peripheral zone
- Central Zone
1. Typical location of benign nodular hyperplasia in the Transition Zone
2. Posterior displacement of both peripheral and central zones
TURP Procedure
Rationale for Transurethral Approach to BPH Ablation

1. Urethra provides perfect site from which to target bilateral anterolateral enlarged TZ.

2. No need to ablate near the rectum.

3. No need to ablate 100% of hyperplastic TZ tissue
Bladder Balloon

Dual-Sected Tubular Transducers (2 x 10 mm long, dual 120 Sectors)

Inflatable high-pressure urethral balloon w/ water flow

Flexible Catheter
Methods: Thermal monitoring and Control

- Real-time PRF-based MRTI at 3-5 axial levels in gland, as well as coronal and sagittal views
- Color thermal map overlay at 47, 52, 60 Deg. C.
- Recent studies have used 3D RThawk software and software control of ablation process by setting up “control points” giving MRTI feedback
Targeted Prostate Thermal Therapy

Transurethral Catheter-Based Devices

Design Schema and Strategies

- Linear Transducer Arrays
- Flexible Delivery Catheter
- Urethral Cooling Balloon
- Multi-Sected Power Control
- Stationary Applicator During Procedure
- Real-time MRTI monitoring/control

Enlarged Transition Zone

Simultaneous Power Control to Multi-Sector Array

Ablation Zones (t43>240 min)

Control Points

Transurethral Applicator w/ Cooling Balloon
Examples of “Acute” Canine Prostate Studies

- Fast selective treatment with dynamic angular control (10-15 min)
- Practical control with MRI feedback
“Chronic” study of canine BPH 5 weeks post-ablation

Axial CE MRI

Corresponding axial gross path
BPH (Transition Zone) Ablation

Canine Prostate

Human Prostate
“Chronic” study of canine BPH 5 weeks post-ablation

Coronal T2-weighted images
Pancreatic Adenocarcinoma

- 4th leading cause of cancer death in the US
- Only 10 to 20% are surgical resection candidates
  - Primarily Whipple procedure for CA of pancreas head
  - Mortality of Whipple procedure is ~5%
- Overall, one year survival rate after presentation is 20%
- If resection is possible, average survival is 18 to 20 months
- While chemotherapy and radiation therapy are used in treatment, pancreatic Ca. is not particularly responsive, presumably due to characteristic metabolic characteristics and low oxygen tension.
Ductal Adenocarcinoma

Rapid T1 Arterial Phase Post Gd

CT Post I-
Pancreatic CA: Thermal therapy

- RFA has been used in very limited studies (Wu, 2006)
  - 25% mortality rate
- Extracorporeal HIFU reported successful in palliation of pancreatic CA (Wu, 2005), but no increase in survival
- Studies of extracorporeal HIFU in swine model (Hwang, 2009)
Opportunities and Problems

• Although palliation is likely a very realistic possibility, Panc Ca. tends to spread early microscopically-?? Is cure a realistic possibility

• Some hope (WU, 2004) that there may be “activated anti-tumor immunity” induced in pancreatic CA patients following HIFU
Extracorporeal HIFU Route
Endoscopic route:
Currently standard for biopsy, procedures
Transgastric Interstitial & Intraluminal Applicator
Design and Operational Schema

EUS-g applicator placement

Goldberg et al. 1999

Intraluminal placement

Fry et al. Endoscopy 2003

Pancreatic Interstitial or Intraluminal Ultrasound Applicator
Multiple Transducers & Sectors (180°)

Tumour

Pancreas

T > 52 °C, t₄₃ > 240 min

Flexible - variable stiffness catheter

Semi-rigid 13-15g

Plastic Collar/Vacuum Assisted

Deployable Sheath

Introducer Sheath Ram/Puncture Set

Tracking coils
Endoluminal Applicator

*Design and Operational Schema*

- Directional Transducer Array
  - Tubular, Planar, or Curvilinear
  - w/Translation & Rotation

- Distensible Balloon for Positioning
- Endogastric Catheter
- Catheter Suction/suture pad for positioning
- Tracking coils
- Fixed Shape Balloon for Cooling Stomach Wall & Coupling
- Tumor
- Pancreas
Pancreatic Head Ca.
Pancreatic Head Ca.
Pancreatic Tail Ca.
Pancreatic Tail Ca.
Pancreatic CA

Arterial Encasement: Short Axis

Uncinate Process Lesion
Endoluminal ablation of pancreatic head tumors
Patient Specific Simulations

Planar & Curvilinear –
- 20-25 mm penetration within pancreas
- Curvilinear improved stomach wall sparing
- 5 min, 3-4 MHz, 10 mm x 12mm
- Dynamic translation extends coverage
Transgastric Interstitial Applicator
POC Device and MRTI

- Directional Tubular Array
- Celcon Catheter w/ cooling

- 2x 1.2-1.5mm x10 mm
- Directional 200°
- 7.5 MHz, 13-14g distal catheter
- 3 mm PEEK – 40 cm proximal
- Multi-slice MRTI
- $T_{\text{max}}$ & Pilot Point control

Control Points
MRTI with Active Device Tracking
Improved Localization of applicator & Setup

- Transducers
- Miniature pancake surface coil

Axial image created by the tracking coil

MRTI during liver ablation through GI track in ex vivo swine

- Device/ anatomy in sagittal image created by the tracking coil
- Large signal localized at the coil position

Oblique axial plane

US aiming

Anatomy image with surface coil

~5.6 MHz, 5 W/cm², 10 min; TE = 5 ms

ΔT = 15 °C
ΔT = 10 °C
ΔT = 5 °C