Quality and Breast Cancer Surgery

BCCA Breast Cancer Update Vancouver, 2009

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Disclosures



Outline

- Cases
- Quality: Definitions and Background
- North American
 - Data
 - Quality Indicators (not a comprehensive review)
 - Initiatives
- Rethink the cases

Case 1 - 45 y.o. female

- Palpable mass X 8 months, family Dr. reassured by negative MMG, eventually U/S core biopsy Invasive ductal ca
- Decision for BCS (occurred 5 weeks after diagnosis)
 MRI performed (indeterminate lesion, cannot biopsy), surgeon discussion
- OR clinically directed lumpectomy (no frozen section), 1 SLN removed (no frozen/touch prep available)
- Path 2.4 Gr III ER –ve HER2+'ve, medial and inferior margin < 1mm, SLN +'ve 6mm focus
- Completion MRM 3 weeks later, postop hematoma reop at 12 hours
- No residual ca in breast, 2/7 nodes positive
- Multidisciplinary case conference presentation
 - Adjuvant Rx postmastecomy RTx, chemo + herceptin

Case 2 - 75 y.o. female

- Abnormal screening MMG 1 cm mass core biopsy inv ductal ca
- Decision for BCS (occurred 2 weeks after diagnosis)
 Surgeon "recommended"
- OR wire localized lumpectomy, 3 SLN removed (touch prep negative), no specimen radiograph
- Path 0.8 cm Gr. I ER +'ve, closest margin 8 mm, all 3 SLN negative H+E, cytokeratins
- Adjuvant therapy Whole breast RT, no med onc

62 y.o. female

- Morbidly obese BMI = 52, DM, CAD, sleep apnea, unable to walk 30 m, cannot lie flat
- 3.5 cm breast mass, MMG core invasive ductal ca
- Lumpectomy under local anesthetic
 - 3.7 cm, gr II, ER –ve, closest margin 1.1 cm
- Multidisciplinary case conference
- Nothing further

Rank Quality

- Which is best ?
 - 1
 - 2
 - 3
- Which is worst?
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 - 3

? Clearer at end of presentation ?

Access to Care: "Domains"

• Presence

• Quality/appropriateness

• Timeliness \rightarrow Most important to patients

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Quality: Definition

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge

- Institute of Medicine, 1990

- Quality = doing the <u>right</u> things <u>well most</u> of the time
 - right = appropriateness
 - well = skill
 - Most = observed vs. expected (100% may not be target)

Poor Quality Care

is when "practices of known effectiveness are being *underutilized*, practices of known ineffectiveness are being *over utilized*, and services of equivocal effectiveness are being utilized in accordance with provider rather than patient preferences (*misuse*)"

-National Cancer Policy Board

Access and Quality – The Importance of the 49th Parallel

• Canada = Timely access

– Wait times

- United States = Quality
 - Pay for Performance
 - Quality measurement National Quality Forum and other initiatives

The Ultimate Pay for Performance Medicare will not pay for:

- Urinary tract infection secondary to catheterization
- Central line infections
- Pressure ulcers occurring in-hospital
- Retained objects after surgery
- Air embolism
- Blood incompatibility reactions
- Sternal wound infection post sternotomy
- In-hospital falls

August 20, 2007

How do we Measure Quality?

- Perspective important can apply to a patient but most refer to a *population*
- 3 common aspects of breast cancer care quality
 - Outcomes of care e.g. disease-free survival, local recurrence
 - Structures of care presence of organizational components
 - e.g. presence of case conference, pathology protocol for SLN
 - Processes of care care actually received/considered
 - e.g. use of radiotherapy post BCS, ALND post +'ve SLN

How do we Measure Quality

- Qualitative "was it good care?"
 - gut feeling of patients, physicians, system
- Measure outcomes
 - Not practical
- Quality indicators
- Adherence to guidelines → Canada well positioned?

Canadian Practice Guidelines for the Care and Treatment of Breast Cancer

- Health Canada sponsored
- Steering Committee with rigorous process
- 16 guidelines; 10 in *CMAJ* supplement 1998, 6 new/updates since, all disseminated through *CMAJ*
- No longer operational or funded, last publication 2004
- Implementation and evaluation little done
- Guideline adherence for 4 surgical measures unchanged over time
 - Latosinsky et al., CMAJ 2007

Guidelines – CCO Staging in Operable Breast Cancer

- ALWAYS post-surgery
- Stage I No routine bone scans, liver U/S, CXR
- Stage II bone scan in all, CXR, liver U/S only if
 ≥ 1 node positive
- Stage III bone scan, liver U/S, CXR in all
- If Rx options limited to hormonal Rx, or where no Rx due to age/co-morbidities, no baseline staging

2003

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- Quality indicators
- \rightarrow Most common
- Adherence to guidelines

Quality Indicators in Breast Cancer

- Ideally, a quality indicator should be:
 - Specific
 - Complete
 - Clearly-worded
 - Feasible
 - Reliable
 - Scientifically valid

Quality Indicators in Breast Cancer

- Systematic review: Schacter et al. BMC Cancer 2006
 - 143 indicators, 58 studies
 - Most indicators related to pathology (42) and appropriate use of chemotherapy (23)
 - Only QOL/ patient satisfaction indicators met scientific rigor

Table 1: Quality Indicators Used to Measure Adherence to Standards of Breast Cancer Care

·····		
Type of Quality Indicator	n	Extent of scientific development as a quality measure*
Diagnosis		
Appropriate use of imaging, sampling (fine-needle or biopsy) within given time-frame	8	N
Adequacy of fine-needle biopsy samples	1	N
Receipt of frozen section of primary operable BC	1	N
Quality of surgical technique, sampling nodes	2	N
Quality of hormone receptor assay	1	N
Quality of life and patient satisfaction relating to diagnosis	2	lac
Appropriate referral to surgeon	2	N
Appropriate (timely) attendance at assessment centre, specialist appointment, surgery, receipt of information by patient	5	N
Efficient diagnosis (few visits to hospital)	1	N
Appropriate evaluation vis a vis guidelines, or at first visit	2	N
Appropriate specialist knowledge of surgeons Treatment	I	N
Appropriate surgical choices – breast conserving, mastectomy, lymph node dissection	7	N
Timely admission for therapeutic surgery	1	N
< 3 operations for breast-conserving surgery		N
Evidence of discussion of surgical options	1	N
Appropriate use, timeliness of initial radiotherapy	6	N
Quality of radiotherapy planning, fractionation, radiation field distribution	7	N
Regional recurrence	1	N
Appropriate use of radiotherapy for regional recurrence, palliation	1	N
Appropriate use (or not) of adjuvant systemic therapy	23	N
Chemotherapy quality of administration - dosages and availability of procedure manual	2	N
Quality of life, satisfaction with treatment	6	la, lac
Participation in decision-making, receipt of sufficient information rel treatment	2	N
Qualifications of doctors	2	N
Appropriate referrals to specialists	2	N
Appropriate treatment choices, sequences	5	N
Followup		
Appropriate followup mammography, use of guidelines	2	N
Recurrence within 5 years	2	N
Appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence	1	N
Reporting Documentation		
Pathology reporting/documentation	42	N
Imaging reporting/documentation - size of mammographic abnormality	1	N
Chemotherapy reporting documentation	2	N

n = number of different quality indicators regarding this type; *extent of scientific development of quality indicator: Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- and on-study data indicating consistently sound psychometric properties; IV = no pre- or on-study psychometric data

Breast Cancer Quality Indicators - Surgery

- 8 measures unclear selection criteria
 - Mastectomy rate (proposed rate 15%-35%)
 - Positive and < 1 mm margin in BCS (proposed rate 10%-30%)
 - Reoperation for BCS (proposed 10%-20%)
 - Number SLN (most 2-4)
 - Number nodes in ALND (12-15)
 - Proportion SLN +'ve undergoing ALND (?)
 - Intraop SLN assessment % (available)
 - Time for Dx to surgery (85%-100% within 4 weeks)
- Meaningful conclusion: Measures assessable, even retrospectively

McCahill et al Arch Surg 2009

National Quality Forum (NQF)

- Non-profit U.S. organization created to develop and implement a national strategy for healthcare quality measurement and reporting
- Goals
 - Principal body to endorse performance measures and quality indicators
 - NQF-endorsed are THE primary standards to measure quality of healthcare in U.S.
 - Increase the demand for high quality healthcare
 - Major driver of quality improvement

National Quality Forum – ASCO/NCCN/ACS CoC

- Measures for Breast Cancer *proposed*
 - RadioRx within 1 year of date of Dx for women < 70 undergoing breast conserving surgery
 - ChemoRx considered within 4/12 of Dx for women < 70;
 AJCC T1c, stage II or stage III
 - Tamoxifen/AA considered within 1 year of Dx for women < 70; AJCC T1c, stage II or stage III
 - Pre-resection needle biopsy
 - SLN Bx or ALND at time of resection for stage I-IIb
 - Use of College of American Pathologists Breast Cancer Protocol

National Quality Forum

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All intended to be applied at hospital level

Breast Cancer Quality Indicators – SLN Surgery

- Modified Delphi approach to select QI
- Retrospective chart review of final QI to assess feasibility of measurement.
- Initial 25 potential QI
- 11 prioritized by panel
 - feasibility assessment based of reporting on these 11 based on 1 year consecutive cohort

Quan et al., Ann Surg Onc 2009

Final SLN Quality Indicators All based on % of patients

<u>Structure</u>

- Serial section path protocol used
- Path report of SLN AJCC-compliant
- Nuclear medicine protocol for colloid injection

Process

- Proper SLN ID (hot/blue/suspicious)
- SLN Bx in T1 undergoing BCS
- SLN Bx concurrent with lumpectomy
- +'ve SLN undergoing ALND
- Inappropriate SLN Bx (e.g. previous inflammatory BC)

Outcome

- SLN Bx +'ve rate
- >1 SLN removed
 - -'ve SLN axillary recurrence

Quan et al., Ann Surg Onc 2009

Breast Cancer Quality Indicators – SLN Surgery

- For each final QI, authors assigned potential target
- Most (but not all) QI measurable via chart or institutional level data

Quan et al., Ann Surg Onc 2009

Quality in Breast Cancer Care The Next Step – Validation Programs

National Consortium of Breast Centers (NCBC)

- Type of center (screening, diagnosis, treatment, combo)
- Type-specific Web questionnaire, must be able to verify responses
 - mostly process measures (e.g.mammography call-back rate, BCS rates)
- Confidential comparison to similar centers
- Based on responses, may qualify as
 - Participant
 - Quality breast center
 - Certified breast center of excellence

Quality in Breast Cancer Care The Next Step – Validation Programs National Accreditation Program for Breast Care (NAPBC)

- ACS-initiated, 15 breast cancer organizations involved in development
- On-site survey
- Mostly structure measures (e.g.case conferences, presence of guidelines, >4% patients on trials)
- Started late 2007
- June 2009 51 accredited centers
- 17 required components 3 "critical"
 - Program leader with authority and responsibility
 - Interdisciplinary care team
 - Interdisciplinary case conferences

Quality in Breast Cancer Care The Next Step – Validation Programs

American Society of Breast Surgeons Quality Program

- "Mastery of Breast Surgery"
- Surgery focused based on ASBS quality indicators
- Individual surgeon focused
- Requires > 3 months all breast OR cases for 3 element:
 - Was pre-OR needle biopsy performed
 - Was surgical specimen oriented for pathology
 - Was confirmation of presence of lesion undertaken before leaving OR
- Confidential peer comparison
 - Expectation of non-threatening environment makes behavioral change more likely

Breast Cancer Quality Indicators – Surgery (Canada)

- Modified Delphi approach
 - Panel 10 surgeons, med onc, rad onc, nurse, pathologist
- 15 final QI prioritized
- Improved Canadian breast cancer health services research
 Decision-making and supportive care
- Gaps in knowledge about quality of breast cancer care in Canada identified
 - Complications, recurrence, diagnostic work-up, accuracy and completion of pathology reports ect.....

Gagliardi et al., Breast Cancer Res Treat 2007

Quality of Breast Cancer Surgery in Canada

- Much work to do
- Limitation
 - Level of evidence for outcome impact of what we do (or do not) think is important
- Details are daunting
 - Data/information sources
 - Surgeon buy-in
 - What is target ?
 - Heterogeneous clinical care environments
 - Ever changing clinical landscape

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Quality issues with all Difficult to quantify quality at the patient level

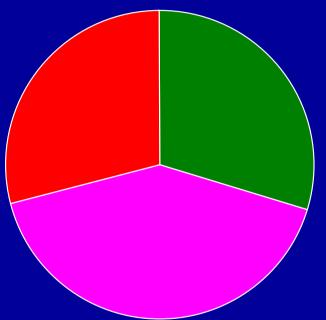
Conclusions: Quality of Breast Cancer Care

- This is not simple
- This is increasingly important
 - We are behind USA, but can do this better
- No single quality measure
- Start somewhere
- Major focus must be on *seamless* data gathering techniques
 - Needs to be built into what we do, how we think



Quality Indicators in Breast Cancer

1. *Staging* (*n*=519)



Understaged
Overstaged/preop
Appropriate

2. RadioRx within 1 year of date of Dx for women < 70 yrs undergoing BCS 158/185 = 84%

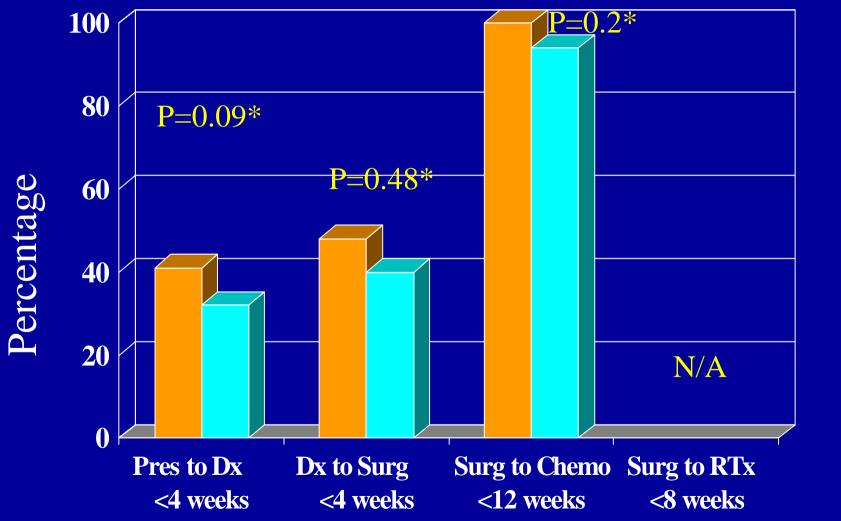
3. Consider Chemo within 4/12 if ER –ve, T1c/Stage II/III, < 70 yrs 66/90= 73%

 4. Tamoxifen/AA considered within 1 year of Dx for women < 70; AJCC T1c, stage II or stage III Not assessable

No associations with any time interval benchmark

Porter et al., Submitted

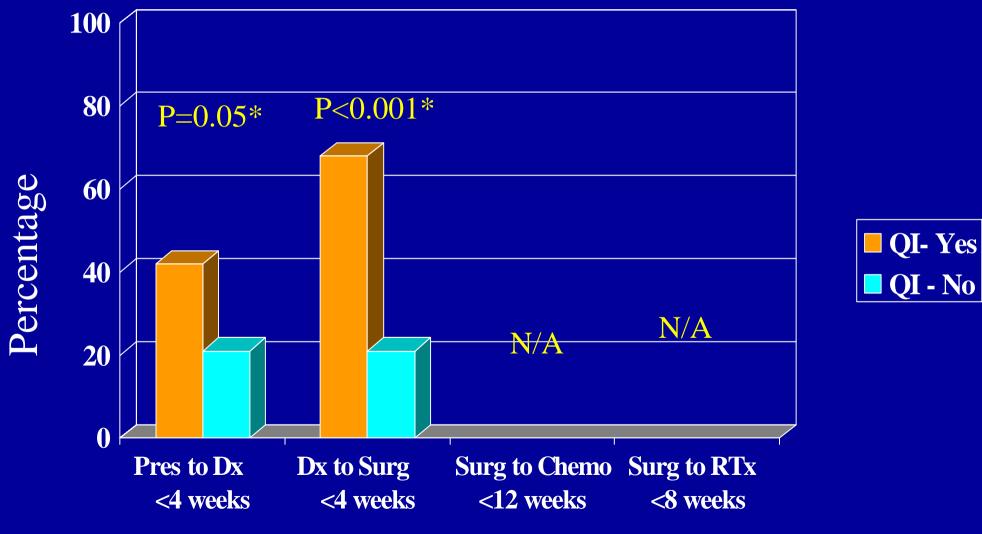
Quality Indicator: RTx in BCS within 1 year (N=185)



QI- Yes QI - No

* Adjusted for significant clinicodemographic factors

Quality Indic. Consider Chemo for ER –'ve N=90



* Adjusted for significant clinicodemographic factors