



Core-Group

Gert Kampmann
Miguel Dumont dos Santos
Peter Fehr
Harald Haueisen - QA
Rahel Kubik-Huch
Wolfgang Oehlschlegel
Christoph Rageth
Martin Sonnenschein

(Luzi Rageth)



QA: Tasks

- Adaptation of existing excel data sheet to internet based data registry (together with Adjumed Services) > www.mibb.ch
- Development of patient information sheets (stereotactic, US- and MR-guided VAB) in German, French, Italian > www.mibb.ch
- Creation of application forms for qualified centers and operators > www.mibb.ch
- Support of electronic data collection
- Proposal of yearly data evaluation
- (Algorithms for „risk lesions“ (radial scar, papilloma, FEA, LN and ADH))
- (Guidelines for follow-up of „risk lesions“)



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Electronic Data Registry I

- Base: AQC-system (Adjumed) of surgeons
- 1st version: „transposition“ and adaptation of existing excel form (2009)
- Modifications (2010):
 - Anonymization of patient ID
 - Mode of detection of lesion (e.g. no „screening US“)
 - Differentiation between diagnostic and therapeutic goal
 - Addition of B-classification
 - Inclusion of pop up- calendars
 - Modification of „complications“ (e.g. technical c., not accessible, breaking off)
 - Degree of lesion removal
 - Sequence of questions



Electronic Data Registry II

• Modifications (2011):

- **Mode of detection**: „other“ will be hidden
- **Method**: „other“ will be hidden
- All fields with **histology**: „phylloides tumour“ will be added
- **Clips**: „Clip with/without gel“ only
- **Histology of open biopsy same side**: „no open biopsy within 3 months“ will be hidden, besides existing „ not indicated“ „indicated, but not performed“ will be added
- **Recommendation**: „open biopsy“ will be hidden, „surgery“ will be added
- **B-Classification**: B1 > B1a, B1b; B5 > B5a, B5b, B5c, B5d

Effective: 1.1.2012



Registry

Minimum yearly cases per center: 20, per qualified operator: 12

Data pooling of 3 consecutive years is feasible
(consensus at annual meeting 2009)

Centers without any completed file/year will be deleted from the list
(consensus at annual meeting 2009)

Only completed data sets count (e.g. incl. open biopsy results in cases of malignancy)

All VAB must be included in the registry, not only the minimum number



Evaluation of Data 2010

- Only completed cases evaluated: 3156 (2009: 2864)
- Univariate distributions (e.g. VAB-methods) and X-linked data
- Modifications of X-correlations to 2010, due to
 - a) newly adapted parameters (e.g. diagnostic/therapeutic goal, B-classif., degree of lesion removal etc.
 - b) more consistent grouping of correlations



Data Evaluation 2010: The Basics

Complications (n, %; +/- „no“) vs.

- VAB-method
- needle type
- degree of lesion removal

-VAB methods	<u>stereo</u>	<u>upright</u>	<u>US</u>	<u>MR</u>
-C total: 6,8%	(7,5%/1856)	(7,2%/194)	(5,0%/916)	(9,2%/184)
-C=100%: heavy bleeding w/o interv.:	64,8%	50,0%	76,1%	64,7%
heavy bleeding w. interv.:	1,4%	0%	6,5%	0%
techn. failure:	11,5%	7,1%	6,5%	5,9%
discontin.:	10,8%	28,6%	8,7%	23,5%



Data Evaluation 2010: The Basics

Complications (n, %; +/- „no“) vs.

- VAB-method
- needle type
- degree of lesion removal

-Needle type	<u>M-tome 8G</u>	<u>M-tome 11G</u>
-C total:	6%(66/1171)	8%(88/1079)
-C=100%: heavy bleeding w/o interv.:	55%	67%
heavy bleeding w. interv.:	0%	5%
techn. failure:	15%	10%
lesion missed:	3%	5%
discontin.:	21%	10%

Stereotactic
core needle:
n = 35



Data Evaluation 2010: The Basics

Complications (n, %; +/- „no“) vs.

- VAB-method
- needle type
- degree of lesion removal

-Needle type	<u>M-tome 8G</u>	<u>M-tome 11G</u>	<u>Suros 9G</u>
-C total:	6%(66/1171)	8%(88/1079)	12%(15/124)
-C=100%: heavy bleeding w/o interv.:	55%	67%	
heavy bleeding w. interv.:	0%	5%	
techn. failure:	15%	10%	
lesion missed:	3%	5%	27%
discontin.:	21%	10%	



Data Evaluation 2010: The Basics

Degree of lesion removal (n, %) vs.

- VAB-method
- needle type
- n/o specimen (grouped)/
needle type

	<u>total</u>	<u>stereo</u>	<u>upright</u>	<u>US</u>	<u>MR</u>
Complete:	50%	43%	28%	75%	21%
Partial:	48%	54%	70%	24%	76%



Data Evaluation 2010: The Basics

Degree of lesion removal (n, %) vs.

- VAB-method
- needle type
- n/o specimen (grouped)/
needle type

	<u>total</u>	<u>stereo</u>	<u>upright</u>	<u>US</u>	<u>MR</u>	<u>M-tome 8G</u>	<u>11G</u>
Complete:	50%	43%	28%	75%	21%	55%	43%
Partial:	48%	54%	70%	24%	76%	44%	56%



Data Evaluation 2010: The Basics

Aim of MIBB vs. VAB-histologies/-B-classifications

- „diagnostic“ vs. VAB-histologies /B-classifications (n, %) totally and per VAB-method
- „mixed“ vs. VAB-histologies /B-classifications (n, %) totally and per VAB-method

-“Diagnostic“ (n=2553):	<u>benign</u> : 55,5%	„ <u>risk</u> “: 18,4%	<u>DCIS</u> : 14,7%	<u>inv. Ca</u> : 9,1%
(2009 (n=2864):	61,6%	16,0%	12,2%	7,8%)
B -classification:	<u>B2</u> : 43,1%	<u>B3</u> : 12,2%	<u>B4</u> : 1,0	<u>B5</u> : 18,6% unbek.: 23,4%
-„Mixed“ (n=254)	stereo VAB: n=38	US-VAB: n=202		
US-VAB:	<u>benign</u> : 75,7%	„ <u>risk</u> “: 17,8%	<u>DCIS</u> : 3,0%	<u>inv. Ca</u> : 2,0%



Data Evaluation 2010: The Basics

- US („handheld“) – VAB:**
- cytology (FNP) (n, %) before US-VAB
 - histology (core, VAB) (n, %) before US-VAB
 - aim „therapeutic“:
 - VAB-histologies /B-classifications (n, %) in US-VAB
 - degree of lesion removal after US-VAB

-No cytology before US-VAB:	80,9% (741/916)
-No histology before US-VAB:	58,2% (533/916)
-No cytology or histology before US-VAB:	44,9% (411/916)
-Histology after US-VAB with aim „therapeutic“:	<u>benign</u> : 235/270 <u>pap. lesion</u> : 24/270
	<u>„risk“</u> : 3/270 <u>inv. Ca</u> : 2/270
-Degree of lesion removal after US-VAB with aim „therapeutic“:	complete: 93,1%



Data Evaluation 2010: The Basics

US („handheld“) – VAB: Indications

(according to consensus statements Senologie 2009;6)

- US lesions, which **despite previous FNP or CNB** require further clarification or removal
- Definitively benign US lesions, which should be removed
- Very small US lesions (< 5mm Ø) with risk not to be detectable again after CNB (require clip placement!)



Data Evaluation 2010: The Basics

US („handheld“) – VAB: Indications

(according to consensus statements Senologie 2009;6)

- US lesions, which **despite previous FNP or CNB** require further clarification or removal
- Definitively benign US lesions, which should be removed
- Very small US lesions (< 5mm Ø) with risk not to be detectable again after CNB (require clip placement!)

Generally: According to the finding, the most effective, simplest, most cost effective and most rapid method to establish the diagnosis should be used



Data Evaluation 2010: The Basics

BIRADS vs. VAB-histologies/-B-classifications

- MG-BIRADS 3-5 vs. VAB-histologies/-B-classifications in stereotactic VAB (add on)
- MG-BIRADS 3-5 vs. VAB-histologies/-B-classifications in stereotactic VAB (stereotactic table)
- US-BIRADS 3-5 vs. VAB-histologies/-B-classifications in US-VAB
- MR-BIRADS 3-5 vs. VAB-histologies/-B-classifications in MR-VAB



Data Evaluation 2010: The Basics

Recommendations after VAB

- Distribution (n, %) including benign histologies
- Distribution (n, %) excluding benign histologies

-Recommendation: „other“: 375/3156

-Recommendation after benign histology (n=1874):
wait and see: 84,8% open b.: **1,5%** repeat VAB: 0,3% „other“: 13,3%

-Recommendation after malign histology (DCIS, inv. Ca) (n=642):
wait and see: **2,6%** open b.: 87,2% repeat VAB: 0,3% „other“: 9,8%



Data Evaluation 2010: The Basics

Histologies

- Distribution of VAB- histologies (n,%) (without histologies after US-VAB with aim „therapeutic“)
- Distribution of open surgery- histologies (n, %)
- Distribution of open surgery- histologies (n, %) without „no open surgery within 3 months“, „not indicated“ and „lost to follow up“

-VAB (n:2886):	<u>ben</u> : 56,8%	<u>B3</u> : 18,6%	<u>DCIS</u>: 13,6%	<u>Ca</u>: 8,6%
-Op.S. (n:3156):	no/no ind./lost to f.u.: 71,3%			
-Op.S.=100	<u>ben</u> : 16,4%	<u>B3</u> : 12,3%	<u>DCIS</u> : 32,2%	<u>Ca</u> : 33,6%



Data Evaluation 2010: The Basics

VAB-histologies (without histologies after US-VAB with aim „therapeutic“)
vs. open surgery- histologies

- standardized to total number of VAB-histologies
- standardized to total number of open surgery- histologies
each time w/o „no open surgery within 3 months“,
„not indicated“ and „lost to follow up“

<u>VAB:</u>	<u>Op.S.:</u>	<u>ben:</u>	<u>B3:</u>	<u>DCIS:</u>	<u>Ca:</u>
-Pap (n:97):				0,0%	0,0%
-Rad (n:36)			11,1%(ADH)		11,1%
-FEA (n:90)				12,5%	3,1%
-ADH (n:45)				17,4%	8,7%
-LCIS/LN (n:56)				7,3%	12,2%
-DCIS (n:368)					17,7%



Data Evaluation 2010: The Basics

Benchmark

- Distribution of VAB- methods (n, %)
- Distribution of MG-BIRADS classes in stereotactic VAB (add on + stereotactic table) (n, %)
- Distribution of US-BIRADS classes in US-VAB (n, %)
- Distribution of MR-BIRADS classes in MR-VAB (n, %)
- Distribution of needles, totally and per VAB-method
- Distribution of clips, totally and per VAB-method

-VAB methods:	<u>stereo-t</u> : 1856	upright: 194	<u>US</u> : 916	<u>MR</u> : 184
(%)	58,8%	6,2%	29,0%	5,8%
-US-VAB (n:916) b. US-BIRADS	2: 16,3%	3: 53,7%	4: 24,6%	5: 2,6%
-Clips (n: 3156):	<u>c</u> : 27,9%	<u>c + gel</u> : 31,8%	<u>biom.</u> : 7,2%	<u>no</u> : 33,2%



Summary

- With present univariate and X-linked evaluations a lot of questions/ hypotheses can be answered
- Individual comparisons (center vs. data pool) possible
- Future longitudinal data evaluation feasible
- Complete and correct data entry essential for consistent data pool