

Direct SB injection for the small malignant  
lesions in superficial location:  
Brief report in 11 patients

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# SB<sup>®</sup>

- 2 Crude drug extracted from Korean pasque flower
- 2 Long history of non-official application in Korean traditional medicine to palliate cryptogenic body masses (neoplasm): initially direct injection, later IV administration
- 2 Limited Korean FDA approval as anticancer agent
- 2 Under clinical trials for several kinds of malignancies

- 2 IV administration: Little systemic adverse effect
- 2 PQ injection: Little local complications even in soft tissue leak
- 2 Role as an alternative in troublesome situations?

Unavailable CTx or RTx:

phobia, intolerance, complications, religion

Lesions in critical locations or cutaneous tissue,  
especially failed in CTx or RTx



# Purpose

- 2 To evaluate clinical efficacy and safety of direct SB injection for small malignant lesions in easily accessible, superficial or critical locations



# Materials and Methods

- 2 IRB approval for clinical trial protocol
- 2 Written informed consent in all patients
- 2 2008 October - 2011 November
- 2 11 patients (M:F 2:9, 44-74 years of age)
- 2 Malignant lesions in superficial or critical location

# Materials and Methods

- 2 Asymptomatic: 4 patients (single or a few lesions)
  - thyroid cancer (n=3)
  - primary lung cancer located in peripheral portion of the lung (n=1)
- 2 Symptomatic: 7 patients
  - metastatic cervical lymphadenopathies (n=2) : local discomfort
  - metastatic subcutaneous nodules (n=2) : pain
  - metastatic external iliac lymphadenopathy (n=1) : ipsil. L/E edema
  - metastasis in rectus abdominis (n=1) : pain
  - metastatic axillary lymphadenopathy (n=1) : discomfort

# Materials and Methods

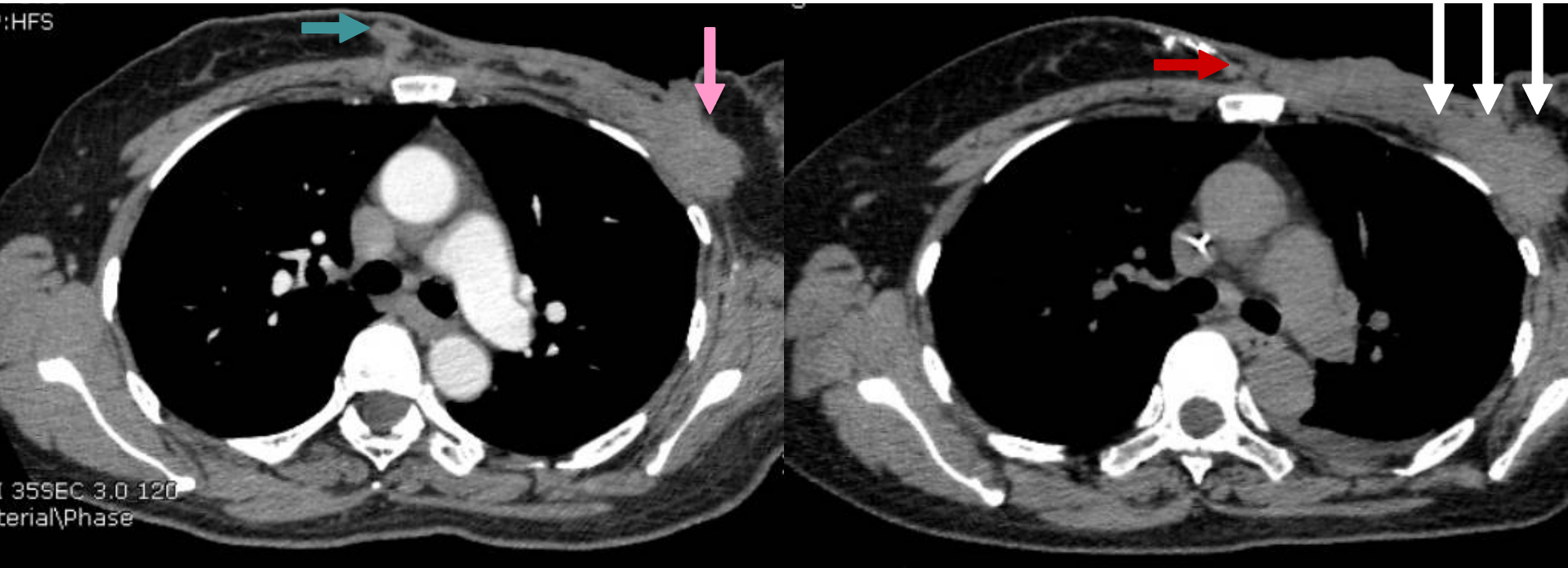
- 2 Imaging study: US, CT, PET-CT
- 2 US or CT fluoroscopy monitoring
- 2 2-3 vials of SB, mixed with CM and N/S  
(SB 1.8cc/1 vial: 0.2cc CM : 1.5cc normal saline)
- 2 24-25G Kovax needle (KV, Korea), 21G PEIT needle  
(Hakko, Japan)

# Materials and Methods

- 2 1 session: daily injection for 2 or 3 days
- 2 1 to 6 sessions:
- 2 End point:
  - Tumor response (CR, PR, SD, PD)
  - Clinical palliation



F/57, recurred breast cancer  
painful metastatic nodule in presternal area



sono-guided  
2v, 1 session

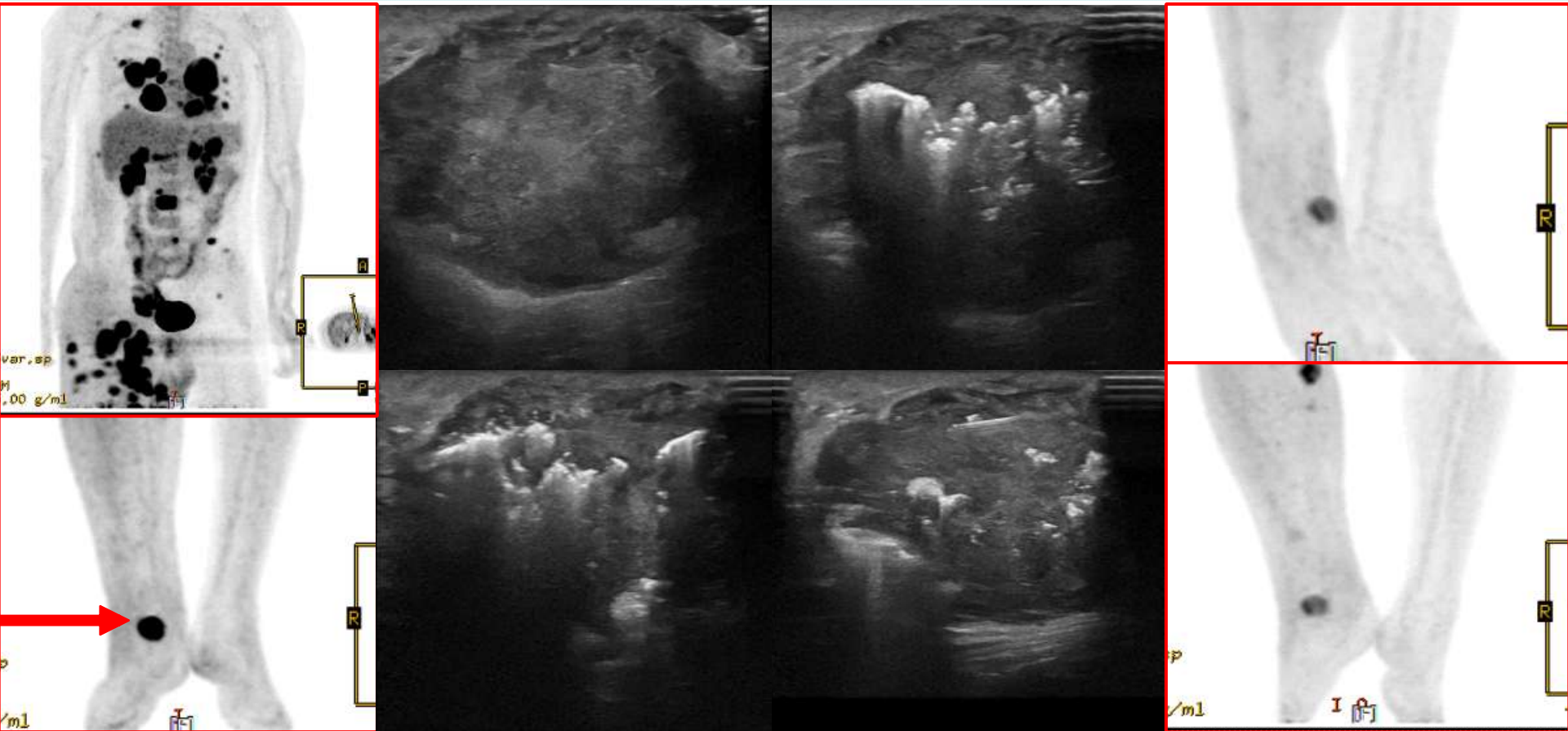
Pain relief w/i  
2 days, VAS 7→2

F/U in 2 months  
PR, no pain

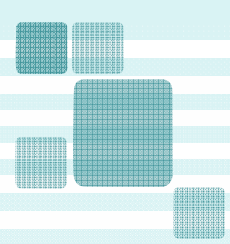
# M/38 Melanoma

Dacarbazine: PD, Ipilimumab: mild response

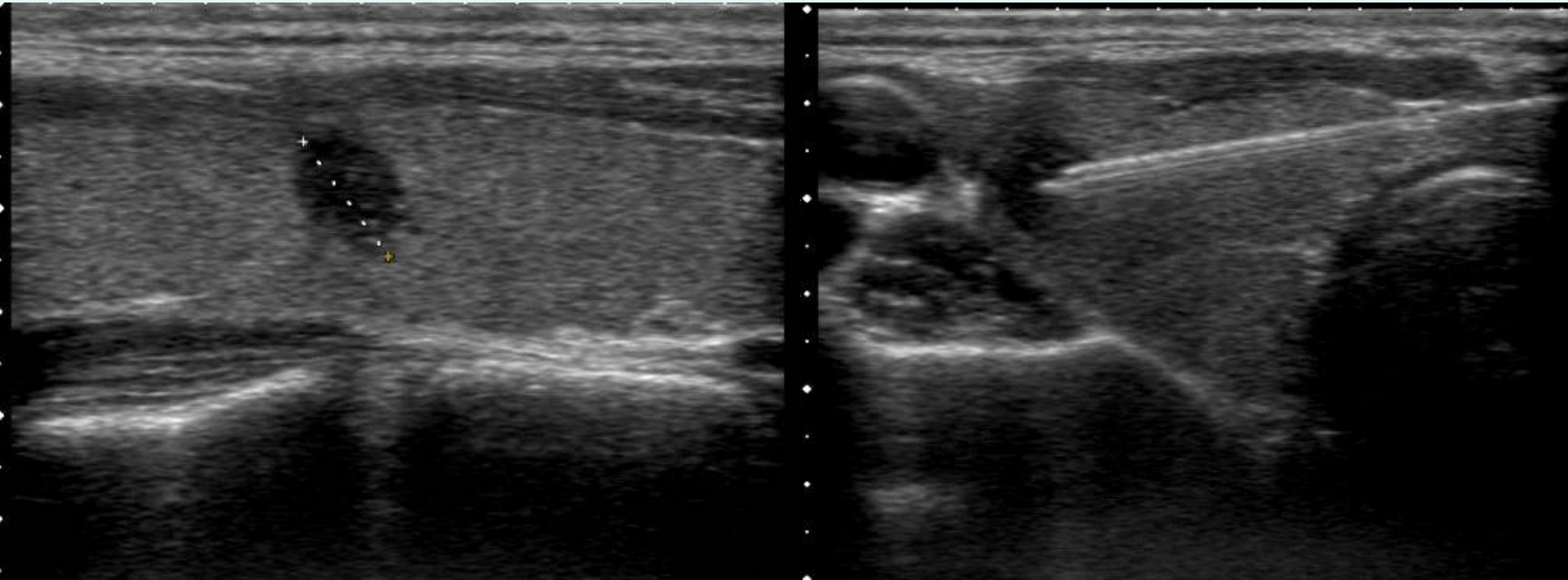
Pain in the lesion in ankle



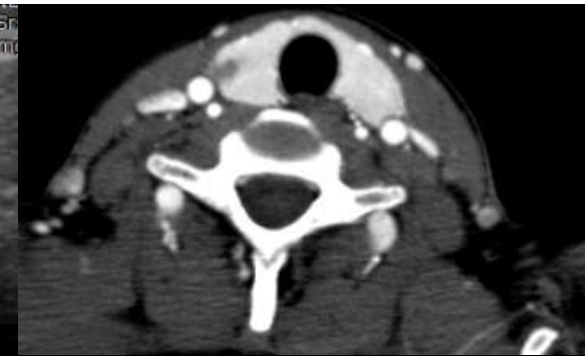
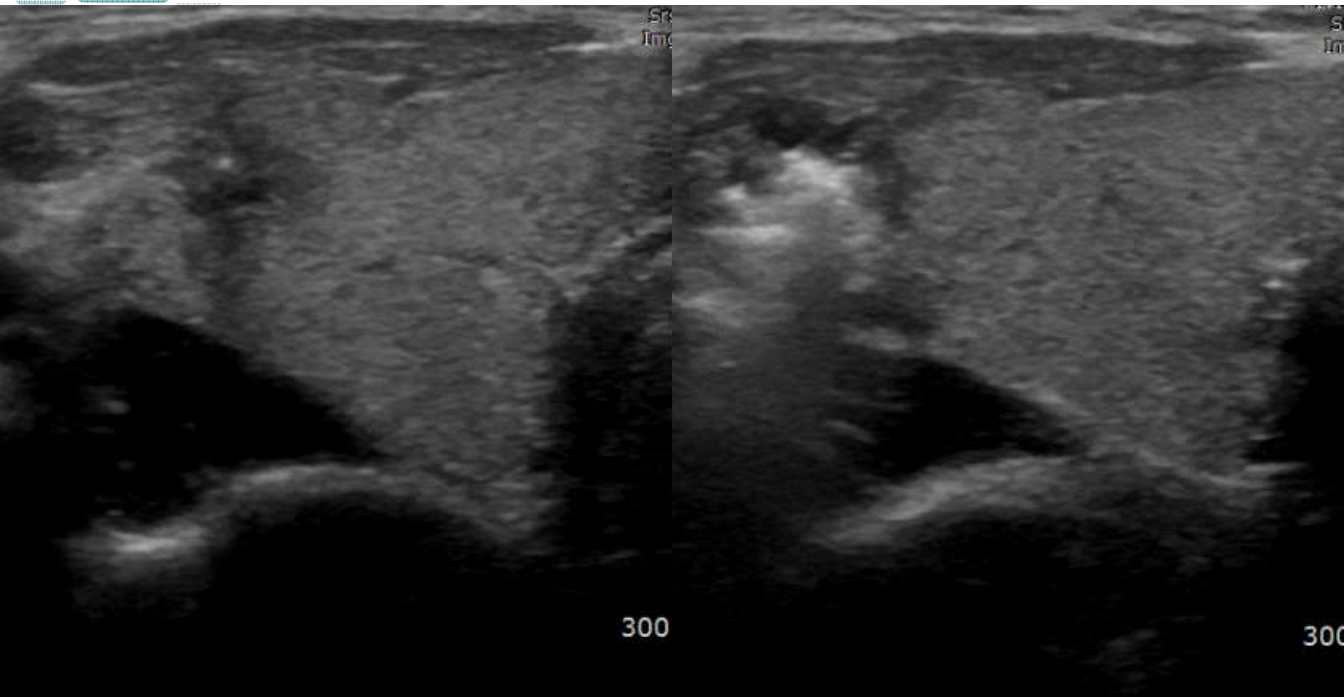
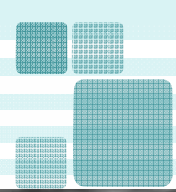
SB injection (3v) x 2 session: pain relief, reduction of size and FDG uptake on PET-CT (3 month f/u)



# F/44, papillary carcinoma in thyroid gland



2009 August



1 month later



2 year later

2010 June: increased size of tumor  
SB 2v, 2 session (3 months interval)  
→ CR in 6 month → no recur in 2 yr



# Result

pts	location	pathology	pre- Tx	local Sx	motive	session	response
1	thyroid	1 <sup>0</sup> cancer	none	none	phobia	5	CR
2	thyroid	1 <sup>0</sup> cancer	none	none	phobia	2	PD (operation)
3	thyroid	1 <sup>0</sup> cancer	none	none	religion	5	PR
4	lung	1 <sup>0</sup> cancer	CTx, RTx	none	intolerable	6	PR (target agent)
5	rec. abdominis	m/colon ca.	RTx	pain	Tx fail	2	SD relief
6	axillary LN	m/breast ca	RTx	discomfort	Tx fail	2	PR not
7	cervical LN	m/stomach ca	CTx, RTx	discomfort	A/E	2	PR relief
8	cervical LN	m/colon ca	CTx, RTx	discomfort	Tx fail	2	SD not
9	SQ nodule	melanoma	dacarbazine	pain	Tx fail	2	PR relief
10	SQ nodule	m/breast ca	CTx, RTx	pain	intolerable	1	PR relief
11	ext. iliac LN	m/ovary ca	CTx, RTx	L/E edema	Tx fail	1	PR relief

A/E: adverse effect  
NCR: near CR

# Results

2 Clinical relief for local symptoms: 5/7

2 Treatment response

CR in 1 patients

PR in 7 patients

SD in 2 patients

PD in 1 patient

2 Complications

transient mild swelling: 3/11

no serious complications in cutaneous tissue

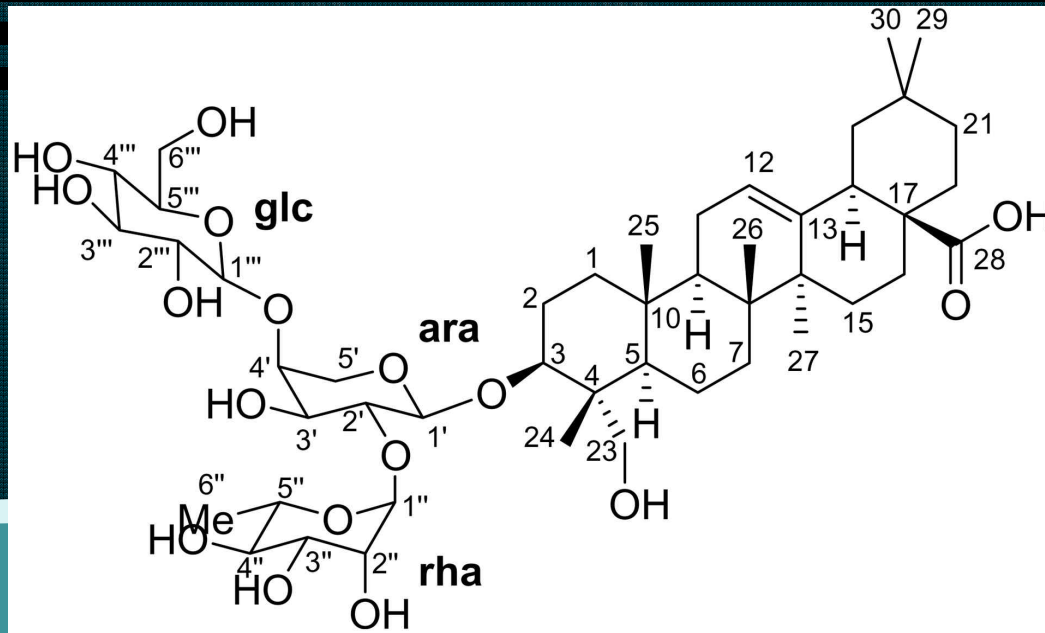
temporary hoarseness: 1/7 (LN near TE groove)

# Discussion

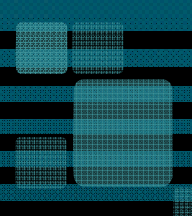

- 2 Standard guidelines (e.g. NCCN)
- 2 Troublesome or equivocal situations
- 2 Small lesions in or near dermis, when
  - CTx or RTx is not available or intolerance?
  - Patients refuse CTx or RTx?
  - General condition is not good for CTx or RTx?
- 2 Thermal ablation (RFA, Cryotherapy)
  - skin burn, frostbite, cosmetic
  - post-procedural pain
  - not available near motor or autonomic nerve

# SB: clinicomedical adaptation

- 2 SB™ (SBP company, Gong-ju, South Korea)
- 2 Crude drug / long history in Korean traditional medicine
- 2 Sporadic experiences for various malignant neoplasm
- 2 Multiple components included
- 2 Anticancer effect: mainly, fulsatila saponin D (mechanism?)





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- 2 Phase III clinical trial lung cancer: about to start
  - 2 Phase II clinical trial for HCC: undergoing
  - 2 Phase II clinical trial for peritoneal carcinomatosis & maintenance therapy in far advanced cancer patients :  
about to start
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# Reports from non-official application in traditional medicine

- 2 Little systemic adverse effect unlike in CTx
- 2 No adverse effect in cutaneous tissue following incidental extravasation
- 2 Promoting general condition
- 2 Anticancer effect? ... milder than chemo-agents in use

# Local injection therapy

- 2 Ethanol in HCC (liver)
- 2 Pingyangmycin in S-C chordoma (JVIR 2011)
- 2 Picibanil in breast cancer (after cryotherapy)
- 2 Artemisinin injection
- 2 Mislto injection

# SB in our trial....

- 2 No concerns for location
- 2 No complications in localized injection  
.... skin, SQ fat, neurovascular bundle
- 2 Good local responses / cost-effective



# Conclusion

- 2 Direct SB injection is safe and efficacious treatment for localized control of the lesions in superficial and critical location, as a 2<sup>nd</sup> or 3<sup>rd</sup> line modality
- 2 Study for inclusion criteria and comparison with other local treatment modalities is needed for dedicated clinical application.

謝

*thank you*

