国家卫生计生委卫生发展研究中心
China National Health Development Research Center

HTA of da Vinci Surgical System in China:

A Case Using Real World Data

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Outline

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- Evaluation Question
- Design & Method
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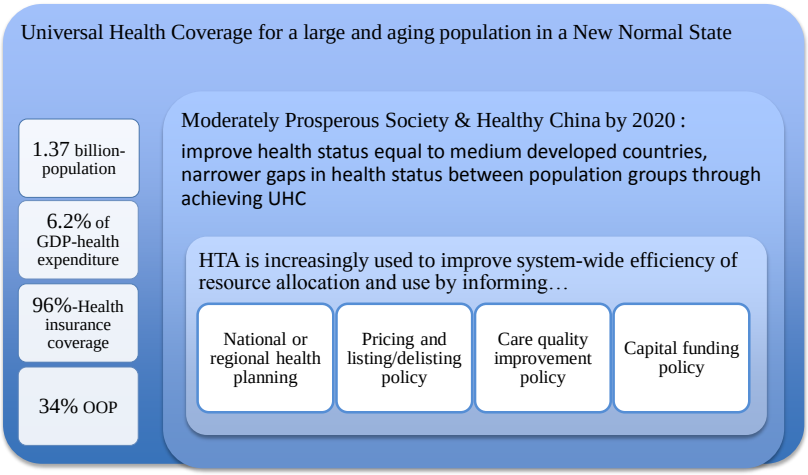
- Conclusion & Policy Recommendation

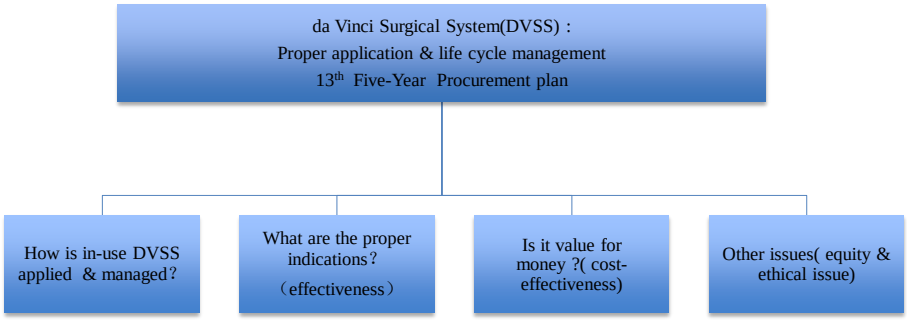
Background



Background

- Emerging market for new health technology: huge middle-class
- New technology Vs Rapid Health Expenditure increase
- **National Medical Device Management Policy (since 2009):**
  - Type A Medical Device: high-tech & expensive device (including **da Vinci surgical system, DVSS**)
  - National Procurement Plan of Type A Medical Device(every five years)
  - Procurement quote for public hospitals
- **12th Five Year Plan(2010-2015):**
  - Rapid HTA by CNHDRC ➡ 34 DVSS
- **13th Five Year Plan(2016-2020):**
  - Life-cycle management of type A device ➡ HTA on in-use DVSS ➡ 13th plan

Evaluation Question



Study Design

Time：Aug 2015- Nov 2016

From the prospective of health system, we evaluated DVSS on:

Dimension	Content	Method	Data type
Technology feature	• Technical advantage& innovation • Potential indication	• Literature review • Expert consultation	• Second-hand data • Qualitative data
Application & management	• Practice in hospital; • Related policy: pricing and reimbursement	• Cross sectional study ; • Expert consultation	• Real world data • Qualitative data
Clinical effectiveness	• Effectiveness of different conditions	• Systemic Review; • Cohort study	• Second-hand data • Real world data
Cost-effectiveness	• Unit cost • Cost effectiveness of selected indication	• Field investigation • CEA based on cohort study • Budget impact analysis	• Second-hand data • Real world data
Equity & ethical issue	• Accessibility; • Affordability	• Qualitative interview • Expert consultation	• Qualitative data

Data Collection & Analysis of Real World Data

- Sample :9 hospitals in 6 cities in 6 provinces

Cross-sectional survey of application :
- Device: region number, maintained
- Operation : number, condition, department
- Human capacity: trained surgeon & nurse
- Analysis: statistic description(mean, portion)

Costing
- Prospective: hospital
- DVSS Vs laparoscopy operation
- Methods : activity based costing(ABC)
- Operation: top 4 operations
- Content: device depriciation, instrument, human, ect
- Analysis: unite cost, budget impact analysis

Quality interview (field visit):
- Topic: application & management
- Key stakeholder:
  - Government decision maker
  - Health insurance policy maker
  - Hospitals director, related departments
  - Surgeon & nurse,
  - Patient

Retrospective Cohort study :
- DVSS Vs laparoscopic operation
- Condition: **radical prostatectomy; Hysterectomy**
- Outcome indicator : operation time; length of stay, rate of positive surgical margin , ect; expenditure in hospital
- Analysis: t-test, multiple linear and logistic regression equation ; incremental cost effectiveness ratio(ICER)

Primary Results of Real World Data

Application & Management

By 2016, in China:

- 57 DVSS in total, 39 devices in 34 public hospitals ,
- 34 devices were installed between 2013-2015
- 389 surgeons, 315 nurses in nationwide
- Operation in rapid increase

Table1 number of DVSS operation in 34 public hospital by region

Region	# of Hospital equipped with device	Total # of operations	# of operation in 2016
East	20	8,001	4,474
Middle	9	4,923	2,693
West	5	1,457	894
Total	34	14,381	8,061

Application & Management

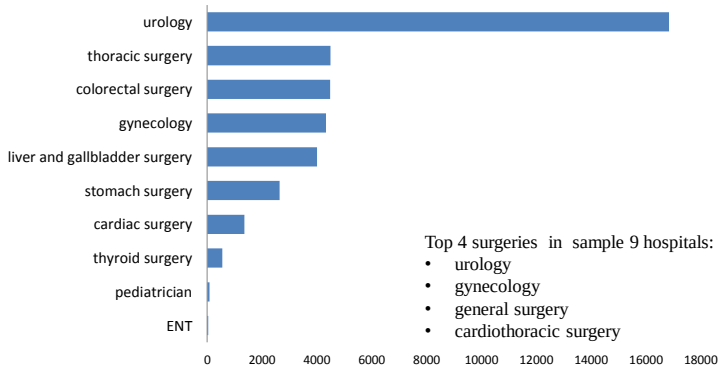


Fig 1 Total number of DVSS operation by clinical department (in 34 hospital)

Application & Management

- No guideline:
  - No national guideline;
  - expert consensus (on 3 condition)
  - protocol& regulation various from regions & hospitals;
- Over usage & Under usage :
  - Over usage: ; application to patients with benign tumors or easy cases to improve efficiency; keen to promote new technology and improve hospital reputation; encouraged to use overtime & develop new operation rapidly
  - Under usage: doubtful attitude to the new technology, Lack of incentive(less profitable than LP), short of skilled surgeons, without enough patient;
  - Safety & Efficiency

Cost

Price of DVSS：

- Device:16-21million yuan (2.3-3.1 million US dollar)
- Annual maintenance : 1 (0.9-1.24) million yuan
- Instrument :15(8-20)thousand yuan /operation

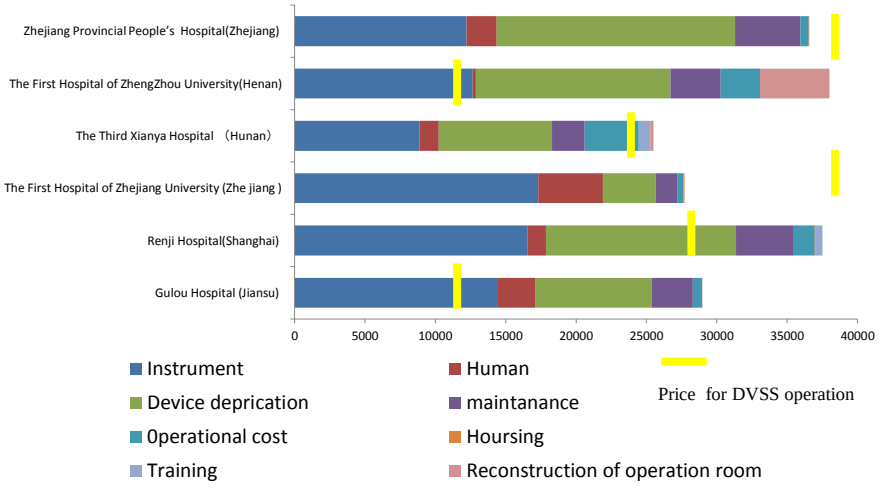
Unit cost of DVSS operation Vs laparoscopy operation

- **30 (17 -42)thousand yuan Vs 10 (8-12) thousand yuan**

Table2 Unit cost of 4 DV operations in 7 hospitals (10 thousand yuan)

Name of hospital	Radical prostatectomy	Radical cystectomy	Hysterectomy	Staging surgery for endometrial cancers
Gulou Hospital (Jiangsu)	2.7-3.1	3.0-3.2	2.3-2.8	2.2-2.8
Renji Hospital(Shanghai)	3.7-3.8	3.9-4.1	3.5-3.6	3.5-3.6
The First Hospital of Zhejiang University (Zhe jiang)	2.3-2.7	-	2.6-2.8	2.4-2.8
The Third Xianya Hospital （Hunan）	2.5-2.6	3.3-3.4	-	-
The First Hospital of ZhengZhou university(Henan)	3.8	-	3.8	3.8
Zhejiang provincial people's hospital(Zhejiang)	3.6-3.7	-	-	-
Zhongshang hospital (Shanghai)	-	-	4.0-4.1	-

Unit cost of radical prostatectomy by DVSS in 6 hospitals



$\bar{x} \pm s$

Cost Effectiveness of Radical Prostatectomy

Both groups:

- Average age > 65 years old,
- intermediate /lower risk prostate caner (PSA < 10 ng/ml, Gleason score < 8, under Ⅱ stage) ,
- Good preoperative condition (ASA Ⅰ-Ⅱ>80%)

Table 3 comparison of general characteristic between two groups

Indicator	Laparoscopy	DVSS
Case	427	421
Age （year，±SD ）*	65.9（8.5）	67.5（7.2）
BMI（mean±SD ）*	22.7（2.8）	24.0（2.8）
Gleason score（mean±SD ）*	6.88（1.0）	7.23（1.0）
PSA before operation（ng/ml, mean±SD ）*	14.72（15.7）	17.18（18.3）
Clinical stage （%）*		
Ⅰa	34.9	40.9
Ⅰb	57.4	40.3
Ⅱa	6.3	18.1
Ⅱb	1.4	0.7
ASA stage （%）		
Ⅰ	45.0	53.2
Ⅱ	39.3	27.3
Ⅲ	15.7	19.5
Comorbidity#（%）	33.0	33.7

***P <0.05;**
 # Comorbidity with heart disease and or diabetes

$\bar{x} \pm s$

Clinical Effectiveness in Short Term

- Compared with laparoscopy , DVSS group：
  - Shorter operation time (-1 hour), less bleeding during operation (-31 ml), shorter LoS and LoS after operation (-2.3 and -1.8 days). – faster bed turnover
  - Shorter indwelling time of drainage tube and catheter (-0.74 and- 2.7 days). – faster recovery
  - No difference in indicators related to long term outcome: rate of positive surgical margin and proportion of complication .

Table 4 Comparison of short term outcomes between two groups

Short-term outcome indicator	Laparoscopy	DV
Operation time(hour，mean±SD)*	3.0（0.8）	2.0（1.3）
Blooding during operation（ml，mean±SD）*	173.8（228.2）	142.5（141.7）
Length of stay（day，mean±SD）*	18.2（6.9）	15.9（5.3）
Length of stay after operation（day，mean±SD）*	11.3（4.6）	9.5（4.32）
Indwelling time of drainage tube（day，mean±SD ）*	7.0（4.83）	6.26（3.4）
Indwelling time of catheter（day，mean±SD）*	14.9（9.5）	12.2（7.5）
Blood transfusion during operation（%）	7.3	11.2
Conversion to open surgery （%）	0.5	0
Positive surgical margin （%）	6.7	7.4
Complication （%）	16.6	20.9

***P<0.05**

Expenditure in Hospital

- Compared to laparoscopy , DVSS group:
  - Higher expenditure : 65 thousand yuan (9.6 thousand US dollar); × 2 laparoscopy.
  - Higher OOP: 67%, 43 thousand yuan(6.3 thousand US dollar); × 3 laparoscopy

Table 5 Expenditure and OOP between two group（yuan）

Indicator	LP	DVSS
Total expenditure（mean±SD ）*	30778.0（12501.7）	64632.6（24171.5）
Out of pocket（mean±SD ）*	15007.4（14339.9）	43389.2（21189.3）

Cost effectiveness

- Compared with laparoscopy , DVSS gourp :
  - Cost-effectiveness is not significant: shortening LoS by 1 day costs 15 thousand yuan more , of which 13 thousand yuan is out-of-pocket expenses.
  - From prospective of health system, taking expenditure saved by shortening one day stay as benefit (4,507 yuan/day, DVSS group), cost-benefit ratio is less than 1.

Table 6 ICER of DVSS radical prostatectomy

ICER*	Meaning	Value （yuan）
ICER1	Incremental cost of reduction of 1 day staying in hospital	15,181
ICER2	Incremental cost to shorten operational time by 1 hour	32,241
ICER3	Incremental OOP to shorten LOS by 1 day	12,727
ICER4	Incremental OOP to reduce operation time by 1 hour	27,030

Budget Impact—Shanghai City

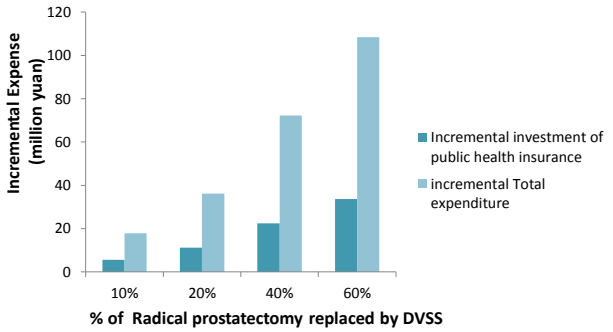
- Prospective ：health system & public health insurance
- Indication：Radical prostatectomy
- Scenario ：DVSS replaces laparoscopy & open surgery
- Time horizon：5 years

Table 7 Parameter of budget impact analysis:

Parameter	value	Parameter	value
Case of indication in Shanghai per year	3904	Average cost of DV（10 thousand yuan）	6.46
Proportion of laparoscopy （%）	80	Operation per robotic per year	300
Proportion of open surgery（%）	20	Cost of DVSS （10 thousand / device）	1877
Expenditure of LP（ 10 thousand yuan per case）	3.08	Annual devaluation（10 thousand / device）	433.54
Expenditure of （10 thousand yuan）	2.50	Annual maintenance （10 thousand / device）	124.00
Proportion of local patient（%）	71	Life time of device（year）	5
Proportion of with CZZG（%）	61	Discount rate（%）	5
Proportion of patient with NRCI（%）	10	Instrument cost （10 thousand/ operation）	1.66
Reimbursement rate of CZZG（%）	60	Operation transformation（10 thousand/ operation）	50
Reimbursement rate of NRCI（%）	45	Life time of operation room（year）	70

Budget Impact—Shanghai

- Considerable impact for just one operation replaced by DVSS in 5 year:
  - Public health insurance: incremental 6- 33 million yuan
  - Total health expenditure: incremental 19-109 million yuan



Conclusion

- Application and management
  - Practice & efficiency varies form regions and hospitals: under use & over use
- Cost
  - The unite cost is much higher than LP operation;
  - Many hospitals can not reclaim cost mainly due to high price of the device& instrument, low efficiency and unreasonable pricing policy
- Cost-effectiveness
  - Compared with LP, DVSS can improve some short-term clinical outcomes of radical prostatectomy patient but with high incremental cost & OOP; uncertain long term cost-effectiveness.
  - Replacement of LP in large scale may have considerable impact on total health expenditure & public health insurance

Recommendation

- To develop standardized guideline and strengthen technology admission & management within public hospitals
- To establish life-cycle management system and collect data especially on long term outcome to inform better planning
- To limit quote in the 13th five year procurement plan and spare space for domestic robotic with much lower price.

Thank you谢谢！

Technology profile

- da Vinci Surgical System (DVSS):robotic laparoscopy surgical system
  - Produced by Intuitive Surgical (USA),
  - Device: console, 3D visualization system, robotic arms
- Advantage ：
  - Facilitate complex surgery in confined & small space using a minimally invasive approach
- Surgery：
  - Worldwide: commonly used in **urology（radical prostatectomy） & gynecology（hysterectomy）**
- Competing technology ：domestic surgical robotic (on the market, 2018）