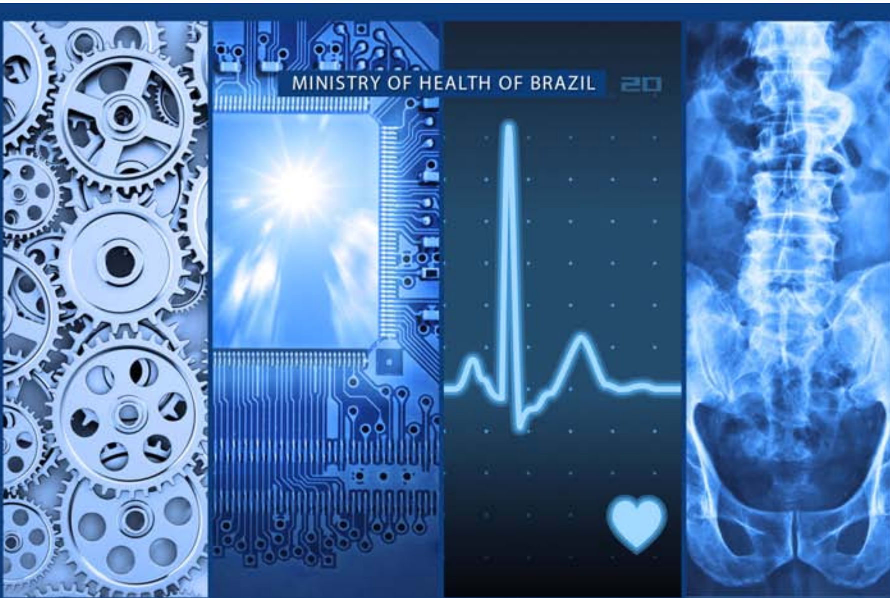

METHODOLOGICAL Guidelines

GUIDELINE for Medical Care Equipment Assessment Studies

Case:
Robotic Surgical System

BRASÍLIA - DF
2014

MINISTRY OF HEALTH OF BRAZIL

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DECLARATION OF POTENTIAL CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interests. The authors do not hold any interest conflicting or relationship with institutions, organizations or individuals that might somehow benefit or may be harmed by the results this validation study for Methodological Guideline for Medical Care Equipment Assessment Studies.

1 EXECUTIVE SUMMARY

OBJECTIVE: Apply a methodological guideline for Robotic Surgery case study.

Technology: Surgical system for use with minimally invasive surgery prostatectomy.

Application in Health: Urology (Procedures: Prostatectomy, Nephrectomy, Radical Nephrectomy Partial Ureteral, Cistoprostatectomias, Pediatric Surgery), Surgery of the digestive system, Gynecology, Head and Neck Surgery, Thoracic and Cardiac Surgery.

Equipment (name, manufacturer, Brand and Model)

da Vinci® Surgical Robotic System: Intuitive Surgical, S2000 - 4-Arm System 3D HD da Vinci®

da Vinci® Robotics Platform: Intuitive da Vinci® - IS 2000

2 CONTEXT OF THE MEDICAL EQUIPMENT EVALUATION STUDY

- Medical equipment: Robotic Surgery System
- Health Application: Prostatectomy
- Alternative Technologies:
    - Open Surgery
    - Laparoscopic Prostatectomy

3 GUIDELINE FOR MEDICAL CARE EQUIPMENT ASSESSMENT STUDIES

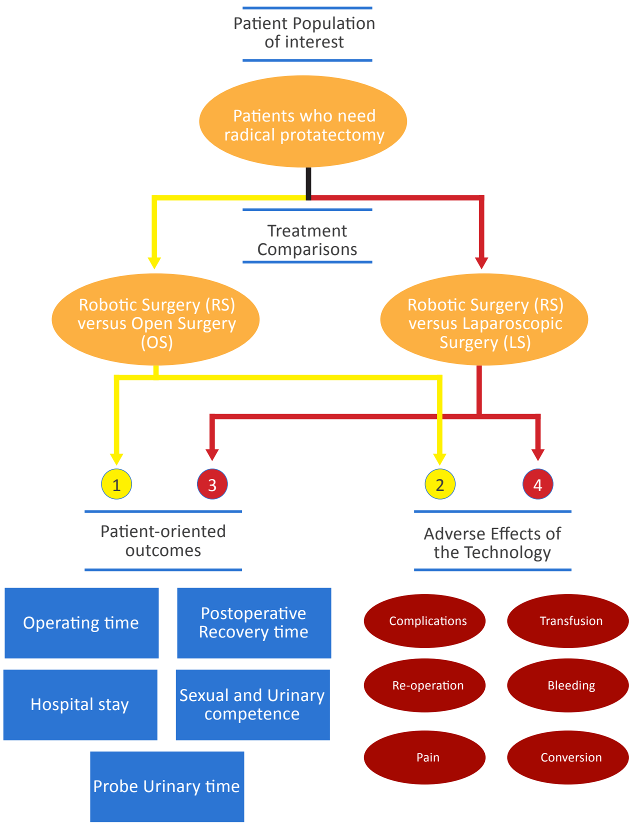
3.1 CLINICAL DOMAIN

This domain of analysis has an important role in elaborating an HTA study, for it is here that seeks in primary studies, such as clinical research, for example, the efficacy and safety of the technology under study. It can be considered that it is the initial step in any HTA study.

STEP 1 - Key Questions

For construction of the key issues, first, we developed an analytical framework, demonstrating the population of interest, intervention (robotic surgery), comparisons (open surgery and laparoscopic surgery) and the outcomes of interest, as showed in Figure 1.

Figure 1 – Analytical Structure considering patients, intervention of interest associated with the comparison of technologies and results



Source: Own Elaboration.

Based on the analytical framework, the key issues were defined as presented in Chart 1.

Chart 1 – Key Question

CR vs CA	1. Did patients who received intervention with the RS obtain significant benefits in terms of patient-oriented outcomes in comparison with LS? 2. Did patients who received with the RS have a significant difference in adverse events compared to LS?
CR vs CL	3. Did patients who received intervention with the RS obtain significant benefits in terms of patient-oriented outcomes in comparison with OS? 4. Did patients who received with the RS have a significant difference in adverse events compared to OS?

Source: Own Elaboration.

Also, key questions were developed in PICO question format as Chart 2.

Chart 2 – PICO Questions

Population	Intervention	Comparison	Outcome
Patients who need radical prostatectomy	RS	OS	Patient-oriented outcomes
	RS	OS	Adverse Effects
	RS	LS	Patient-oriented outcomes
	RS	LS	Adverse Effects

Source: Own Elaboration.

STEP 2 - Inclusion and Exclusion Criteria

1. POPULATION:
   - Adult men with an indication for prostatectomy surgery.

2. INTERVENTION:
   - Robotic surgery system.

3. STUDY DESIGN:
   - Systematic Reviews, randomized controlled trials (RCTs) and, when unavailable, observational studies (prospective, retrospective and controlled clinical trials).

4. OUTCOMES:
    - Patient–oriented: Operation time, hospital stay, sexual and urinary competence, probe urinary time, postoperative recovery time;
    - Adverse Events: Complication, transfusion, re-operation, bleeding, pain, conversion.

5. PUBLICATION FORM:
    - Studies in languages: English, Portuguese, Spanish;
    - Studies by the same author and subject are considered the latest and the greatest amount of present results.

STEP 3 - Scientific Literature Search

The search we used the MeSH terms:

- Robotics;
- Laparoscopy;
- Surgical Procedures, Operative;
- Prostatectomy.

Chart 3 – Search strategy with the terms used and studies selected

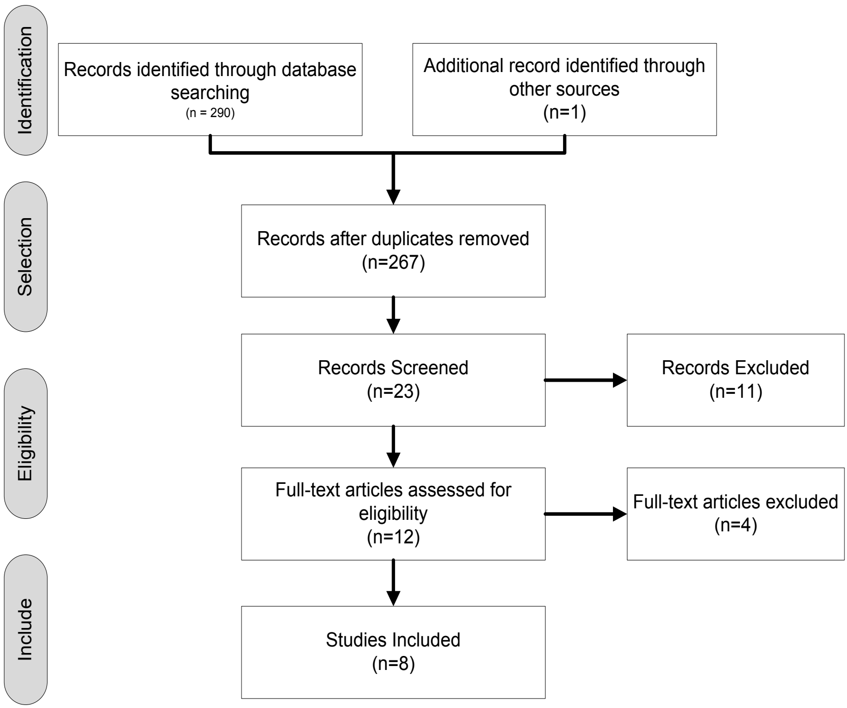
Databases	Terms	Results	Selected studies	Available studies
Medline (via Pubmed)	((“Prostatectomy”[Mesh] AND “Robotics”[Mesh]) AND “Laparoscopy”[Mesh]) AND “Surgical Procedures, Operative”[Mesh] AND (“humans”[MeSH Terms] AND “male”[MeSH Terms] AND (English[lang] OR Spanish[lang] OR Portuguese[lang]) AND (“middle aged”[MeSH Terms] OR “aged”[MeSH Terms]) AND “2007/04/23”[PDat] : “2012/04/20”[PDat])	223	33	33
CRD	(Robotics) AND (Laparoscopy) AND (Surgical Procedures) AND (Prostatectomy) IN DARE, HTA FROM 2007 TO 2012	1	1	1
Cochrane (via bireme)	Robotics and laparoscopy and surgical and procedures and prostatectomy	6	2	2
LILACS (via bireme)	(Robotics) AND (Laparoscopy) AND (Surgical Procedures) AND (Prostatectomy)	8	1	1
Web of Science	Topic=(Robotics) AND Topic=(Laparoscopy) AND Topic=(Surgical Procedures) AND Topic=(Prostatectomy). Refined by: Languages=(ENGLISH OR SPANISH) AND Document Type=(ARTICLE OR REVIEW). Timespan=All Years. Lemmatization=On	52	9	6
TOTAL		290	47	36

Source: Own Elaboration.

STEP 4 - Study Selection and Evidence quality analysis

As a way to demonstrate how it was performed the study selection, a flow chart was developed as shown in Figure 2. Found in the five databases surveyed, a total of two hundred and ninety (290) publications. These, after analysis and comparison with the criteria of inclusion and exclusion, eight (8) studies were included.

Figure 2 – Study selection flowchart



Source: Own Elaboration.

In the survey found two (2) reports on health technology assessment, which contained systematic reviews. Thus, they were evaluated according to the table containing the parameters necessary for evaluating the quality of evidence from systematic reviews. The results of this evaluation are shown in Chart 4.

Chart 4 – Quality of Evidence from Systematic Reviews

Study	Ho C. et al., 2011	Lópes, S. E. et al., 2008
Search	MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Embase, BIOSIS Previews, PubMed, CINAHL, and The Cochrane Library	CRD (HTA, NHS EED e DARE); Cochrane plus; Embase; Medline; CINAHL via Ovid
Number of studies	51	23
Primary studies Quality	There are no RCTs. All studies are no-randomizes comparative (prospective or retrospective)	There are no RTCs. All studies are controlled, in most prospective. Many studies have a deficiency in the baseline comparison.
Evaluation	The studies were evaluated according to a clinical trials evaluation form. The form contains five categories (A,B,C,D and E) in descending order of quality	The studies were evaluated with a checklist developed by Guyatt publications (1993,1994)
Participants profile	Patients undergoing robotic surgery for the prostatectomy indication	Patients (adult men) with prostate cancer or patients (adult men) with radical prostatectomy indication
Comparison	40 studies: the comparator was OS. 09 studies: was LS. 02 studies have both comparisons.	15 studies: the comparator was OS. 08 studies: was LS.
Conflict of interest	The authors affirm that there is nothing to declare	The authors declare that they have no interests that can influence the study

Source: Own Elaboration.

STEP 5 - Summary of Evidence and Clinical Recommendations

The results of the studies analyzed are presented in two (2) Chart 5 and 6. Chart 5 shows the results of the two (2) studies evaluating health technology, and Chart 6 presents the results of retrospective studies analyzed.

Chart 5 – Reports results of health technology assessment

<table>
<tr><th>Author reference, date and country</th><th>Agency</th><th>Focus, basic methodology, main findings and conclusions and recommendations</th></tr>
<tr><td>Ho C. et al.
2011
(Canada)</td><td>Canadian Agency for Drugs and Technologies in Health (CADTH)</td><td>Objectives:
Assess the clinical effectiveness and cost-effectiveness of robotic surgery compared to open surgery or laparoscopic procedure in cases of prostatectomy, nephrectomy, hysterectomy and heart surgery.

Methodology:
Systematic review and meta-analysis. Bases: MEDLINE, MEDLINE citations in process and not indexed; EMBASE; BIOSIS Previews; PUBMED; CINAHL; The Cochrane Library. Language: English and French.
Selection criteria:
Study design: ECR ' s, when not available observational studies.
Population: Individuals who underwent robotic surgery in one of the four selected indications.
Intervention: robotic surgery using the da Vinci ® System
Comparison: open surgery and Laparoscopy.
Peer review (reviewers ' 2)
Evaluation of studies: studies are classified as (A) to (E), through a modified assessment of Hailey et.al, 2004.

Results:
51 studies focused on Prostatectomy.

Clinical Part: robotic surgery compared to open surgery
<table>
<tr><th>Outcome</th><th>Nº of Studies</th><th>Sample</th><th>I², P value</th><th>Results (IC 95%)</th></tr>
<tr><td>Operation time (minutes)</td><td>19</td><td>5,201</td><td>98,00%, < 0,000001</td><td>WMD = 37,74 (17,13 , 58,34)</td></tr>
<tr><td>Hospital stay (days)</td><td>19</td><td>5,554</td><td>98,9%,< 0,000001</td><td>WMD = -1,54 (-2,13 , -0,94)</td></tr>
<tr><td>Complication</td><td>15</td><td>5,662</td><td>64,01%, 0,0004</td><td>RR = 0,73 (0,54 , 1,00)</td></tr>
<tr><td>Bleeding (mL)</td><td>21</td><td>5,568</td><td>99,4%,< 0,000001</td><td>WMD = -470,26 (-587,98 , -352,53)</td></tr>
<tr><td>Transfusion</td><td>18</td><td>8,730</td><td>62,3%, 0,0002</td><td>RR = 0,20 (0,14 , 0,30)</td></tr>
<tr><td>Urinary competence (3 months)</td><td>5</td><td>845</td><td>66,4%, 0,05</td><td>RR = 1,15 (0,99 , 1,34)</td></tr>
<tr><td>Urinary competence (12 months)</td><td>8</td><td>2,022</td><td>40,0%, 0,11</td><td>RR= 1,06 (1,02 , 1,10)</td></tr>
<tr><td>Sexual competence</td><td>7</td><td>1,726</td><td>70,1%, 0,003</td><td>RR = 1,55 (1,20 , 1,99)</td></tr>
</table>
</td></tr>
</table>

Continue

Continuation

<table>
<tr><th>Author reference, date and country</th><th>Agency</th><th>Focus, basic methodology, main findings and conclusions and recommendations</th></tr>
<tr><td>Ho C. et al. 2011 (Canada)</td><td>Canadian Agency for Drugs and Technologies in Health (CADTH)</td><td>Robotic surgery compared with Laparoscopy
<table>
<tr><th>Outcome</th><th>Nº of Studies</th><th>Sample</th><th>I², P value</th><th>Results (IC 95%)</th></tr>
<tr><td>Operation time (minutes)</td><td>9</td><td>1,415</td><td>99,8%, <0,00001</td><td>WMD = -22,79 (-44,36 , -1,22)</td></tr>
<tr><td>Hospital stay (days)</td><td>7</td><td>1,235</td><td>76,2%, 0,0003</td><td>WMD = -0,80 (-1,33 , -0,27)</td></tr>
<tr><td>Complication</td><td>9</td><td>1,845</td><td>60,0%, 0,01</td><td>RR = 0,85 (0,50 , 1,44)</td></tr>
<tr><td>Bleeding (mL)</td><td>10</td><td>1,655</td><td>90,0%, <0,00001</td><td>WMD = -89,52 (-157,54 , -21,49)</td></tr>
<tr><td>Transfusion</td><td>7</td><td>1,820</td><td>0%, 0,83</td><td>RR = 0,54 (0,31 , 0,94)</td></tr>
<tr><td>Urinary competence (3 months)</td><td>3</td><td>556</td><td>66,4%, 0,05</td><td>RR = 1,10 (0,90 , 1,34)</td></tr>
<tr><td>Urinary competence (12 months)</td><td>2</td><td>400</td><td>17,7%, 0,27</td><td>RR = 1,08 (0,99 , 1,18)</td></tr>
</table>

Conclusion:
RS versus OS:
• RS had a duration of 38 minutes more than the OS;
• RS hospital stay was 1.5 lower than OS;
• RS showed a reduced in 80% the risk of transfusion compared with OS;
• RS showed a reduced in 27% the risk of complications compared with OS.

RS versus LS:
• RS operation time was 23 minutes faster than LS;
• Hospitalization time RS was 0.8 lower than LS;
• RS showed a reduced in 46% the risk of transfusion compared with LS.
• RS compared with LS presented an inconclusive result for complication outcome.</td></tr>
<tr><td>Lópes, S. E. et al., 2008 (Spain)</td><td>Unidade de Avaliação de Tecnologias Sanitárias (UETS) da Comunidade de Madrid. Agencia Latín Entralgo.</td><td>Objectives:
Evaluate the efficacy and safety of the da Vinci ® Surgical device in surgical interventions and assess the costs derived from use.

Methodology:
Systematic Review and Metanalysis. Bases: CRD HTA database, NHS EED and DARE; Cochrane plus; EMBASE; MEDLINE; CINAHL via OVID. Published from 2002 to 2008.
Inclusion criteria:
Study with a control group that buys the CR with any other surgical technique.</td></tr>
</table>

Continue

Continuation

<table>
<tr><th>Author reference, date and country</th><th>Agency</th><th>Focus, basic methodology, main findings and conclusions and recommendations</th></tr>
<tr><td>Lópes, S. E. et al., 2008 (Spain)</td><td>Unidade de Avaliação de Tecnologias Sanitárias (UETS) da Comunidade de Madrid. Agencia Latín Entralgo.</td><td>Original articles, studies conducted in humans.
Exclusion criteria:
Series of cases, comments, reviews, letters, books or chapters of books.
Animal studies, studies in cadavers.
Quality assessment of studies included: through checklist developed from Guyatt GH publications and working employees of evidence-based medicine (Guyatt, 1993; 1994).

Results:
Robotic surgery compared to open surgery
<table>
<tr><th>Outcome</th><th>Nº of Studies</th><th>I^2, P value</th><th>Results (IC 95%)</th></tr>
<tr><td>Operation time (minutes)</td><td>5</td><td>90%, 0,00001</td><td>WMD =27,77 (9,34 , 84,39)</td></tr>
<tr><td>Hospital stay (days)</td><td>7</td><td>99% , 0,00001</td><td>WMD = -1,58 (-2,57 , -1,52)</td></tr>
<tr><td>Complication</td><td>4</td><td>49% , 0,12</td><td>RR = 0,41 (0,24 , 0,78)</td></tr>
<tr><td>Bleeding (mL)</td><td>9</td><td>94% , 0,00001</td><td>WMD = -473,28 (-581,32 , -356,13)</td></tr>
<tr><td>Transfusion</td><td>4</td><td>80%, 0,0001</td><td>RR= 0,08 (0,00 , 1,02)</td></tr>
<tr><td>Urinary competence (3 months)</td><td>2</td><td>73%, 0,05</td><td>RR= 1,83 (0,94 , 5,01)</td></tr>
<tr><td>Urinary competence (6 months)</td><td>2</td><td>0%, 0,60</td><td>RR = 2,45 (1,11 , 5,61)</td></tr>
<tr><td>Pain</td><td>2</td><td>100%, 0,00001</td><td>RR = -1,98 (-5,91 , 1,54)</td></tr>
<tr><td>Probe urinary time (days)</td><td>3</td><td>96%, 0,00001</td><td>WMD = -4,51 (-8,57 , -3,38)</td></tr>
</table></td></tr>
</table>

Continue

Conclusion

<table>
<tr><th>Author reference, date and country</th><th>Agency</th><th>Focus, basic methodology, main findings and conclusions and recommendations</th></tr>
<tr><td>Lópes, S. E. et al., 2008 (Spain)</td><td>Unidade de Avaliação de Tecnologias Sanitárias (UETS) da Comunidade de Madrid. Agencia Laín Entralgo.</td><td>Robotic surgery compared with laparoscopy
<table>
<tr><th>Outcome</th><th>Nº of Studies</th><th>I^2, P value</th><th>Results (IC 95%)</th></tr>
<tr><td>Operation time (minutes)</td><td>6</td><td>94%, 0,00001</td><td>WMD = -0,06 (-26,48 , 28,39)</td></tr>
<tr><td>Hospital stay (days)</td><td>3</td><td>92%, 0,07</td><td>WMD = -0,28 (-1,04 , 0,78)</td></tr>
<tr><td>Complication</td><td>5</td><td>83%, 0,0001</td><td>RR = 0,32 (0,28 , 3,01)</td></tr>
<tr><td>Transfusion</td><td>5</td><td>45%, 0,13</td><td>RR = 0,01 (-0,01 , 0,03)</td></tr>
<tr><td>Urinary competence (1 month)</td><td>2</td><td>0%, 0,68</td><td>RR = 2,00 (1,43 , 5,87)</td></tr>
<tr><td>Probe urinary time (days)</td><td>3</td><td>43%, 0,13</td><td>WMD = 0,03 (-0,57 , 0,54)</td></tr>
<tr><td>Conversion for OS</td><td>5</td><td>4%, 0,38</td><td>RR = -0,01 (-0,03 , 0,00)</td></tr>
<tr><td>Total conversion</td><td>5</td><td>47%, 0,11</td><td>RR = 0,00 (-0,01 , 0,01)</td></tr>
</table>
Conclusion:
RS versus OS:
• RS had a longer operation time, less bleeding, a decreased number of complications, hospital stay, urinary probe time and lower urinary incontinence.
• RS versus LS:
• RS had fewer conversions than LS and a greater recovery of sexual and urinary incontinence. RS and LS did not differ with operation time, complications, bleeding, blood transfusions, hospital stay and use time of the urinary catheter.

Analysis Summary:
• There is little evidence that RS has advantages in performing radical prostatectomy: fewer conversions compared with OS and a greater recovery of incontinence than LS.</td></tr>
</table>

Source: Own Elaboration.

Chart 6 – Results from other studies reviewed

Studies	Type of the study / Population	Outcome	RESULTS (IC 95%)
Barry, M. J. et al., 2012	• Retrospective Study; • Patients diagnosed with prostate cancer with indication of radical prostatectomy undergoing RS or OS; Group A: RS; n= 406 Group B: OS; n= 220 • Random sample of medical records; • Collection period: 1 August 2008 to 31 December 2008	Urinary Incontinence problems (%) Sexual function problems (%)	No Problem: Group A = 13,2; Group B =19,2 Very small: Group A = 29,8; Group B = 29,4 Small: Group A = 23,7; Group B = 24,3 Moderate: Group A = 21,6; Group B = 18,2 Big: Group A = 11,7; Group B = 8,9 No Problem: Group A = 2,3; Group B =2,9 Very small: Group A = 2,0; Group B = 3,8 Small: Group A = 7,3; Group B = 4,3 Moderate: Group A = 21,7; Group B = 17,6 Big: Group A = 65,8; Group B = 71,4
Park, J. W. et al., 2011	• Retrospective Study; • n=106 • Patients with indication of radical prostatectomy Group A: LS; n= 62 Group B: RS; n= 44	Operation Time (minutes) Transfusions Hospital stay (days – medium) Probe urinary time (days – medium)	Group A = 308 (158 , 456) Group B = 371 (240 , 720) P = 0,00 Group A = 0 Group B = 1 Group A = 7 Group B = 7 P = 0,71 Group A = 9 Group B = 8 P = 0,15
Lallas, C. D. et al., 2010	• retrospective study • n=1.047 • Patients with indication of radical prostatectomy Group A: CR n = 626 Group B: CA n = 421 • 2001 to 2009	Complications: symptomatic lymphocele (%) Lower limbs neuropraxic (%) Obturator Nerve Injury (%)	Group A = 3 (0,6) Group B = 5 (1,5) Group A = 1 (0,2) Group B = 0 Group A = 1 (0,2) Group B = 0 Total: Group A = 5 (1,1) Group B = 5 (1,5)

Continue

Conclusion

Studies	Type of the study / Population	Outcome	RESULTS (IC 95%)
Gainsburg, D. M. et al., 2010	• retrospective study • Database of Urologic Surgery and anesthesia patients who underwent retro pubic radical prostatectomy • n=681 Group A: CA n = 106 Group B: CR n = 575 • 2002 to 2008	Operating time (minutes) Estimated blood loss (mL) Postoperative time (minutes) Length of stay (days)	Group A = 243 (125 , 480) Group B = 119 (60 , 270) P < 0,01 Group A = 1.200 (250 , 5.000) Group B = 50 (5 , 400) P < 0,01 Group A = 237 (118 , 665) Group B = 167 (56 , 1.392) P = 0,04 Group A = 3 (2 , 5) Group B = 1 (1 , 15) P < 0,01
Gonzalez, P. J. A. et al., 2010	• retrospective study • Intern Database • Patients who performed Urological surgery • n=3.622 surgery Group A: CA n = 1.407 Group B: CL n = 320 Group C: CR n = 137 • 1997 to 2007	Operating time (minutes) Length of stay (days)	Group A = 227,45 (90 , 495) Group B = 273,68 (160 , 575) Group C = 339,81 (200 , 525) Group A = 6,56 (2 , 49) Group B = 4,91 (2 , 39) Group C = 4,71 (2 , 21)
YU, H et al., 2012	• cohort study • Database • Patients undergoing CR, CA and CL in cases of radical prostatectomy • n= 21.834 Group A: CR = 52,7% Group B: CL = 2,8% Group C: CA = 44.4% • 2008	Complications (%) Blood transfusion (%) Length of stay (mean)	Group A = 864 (8,4) Group B = 68 (14,5) Group C = 869 (10,1) Group A = 168 (8,4) Group B = ----- Group C = 452 (5,2) Group A = 1,7 (3,3) Group B = 2,0 (3,2) Group C = 2,4 (4,0)

Source: Own Elaboration.

Based on a review of the results from scientific literature to assess the robotic surgery system:

- Prostatectomy performed using robotic surgery system showed a higher operating time compared with open surgery (HO et al., 2011; MARTÍNEZ SM et al. 2,009; GONZALEZ et al., 2009). Already in comparison with laparoscopic surgery, robotic systems did not show a significant difference.
- The hospital stay was less with the robotic surgery system use compared with open surgery (HO et al., 2011; MARTÍNEZ SM et al., 2009; GONZALEZ et al., 2009).
- The studies showed a lower blood loss in robotic surgery compared to open

surgery (HO et al., 2011; MARTÍNEZ SM et al., 2009; GAINSBURG et al., 2010). Compared with laparoscopic surgery, robotic surgery showed no significant differences with respect to this outcome.

- The robotic surgery system was associated with the improvement of the urinary return and sexual function when compared to the others technologies (HO et al., 2011; MARTÍNEZ SM et al., 2009; PARK et al., 2011).
- Within a systematic review, two studies have demonstrated a decrease of pain reported by the patients with the robotic surgery use compared to open surgery.
- Studies indicated a decrease of urinary catheter stay in the group that underwent robotic surgery, however, it was found that the studies are heterogeneous regarding this outcome.
- Regarding the recovery time after surgery, a study showed that it was less with the robotic surgery.

SUMMARY OF ANALYSIS

- It was possible to carry out an analytical framework;
- Was found a large number of studies, but were slowly within the defined inclusion and exclusion criteria;
- The equipment fits in the class 01-product Framework – low risk;
- The studies analyzed present high heterogeneity;
- The scientific evidence showing favoritism to robotic surgery system, but with no significant magnitude, in addition, low quality of the evidence.

3.2 ADMISSIBILITY DOMAIN

This domain aims to provide the reviewer with legal and technical support to better evaluate the pertinence of a request, be it from the population or of a technical nature.

- ANVISA Product Registration:

Chart 7 – List of equipment found by the term "Robotic"

Company Name	H STRATTNER E CIA LTDA		
CNPJ	33.250.713/0001-62	Authorization	1030286
Product	SISTEMA ENDOSCÓPICO ROBÓTICO DA VINCI - INTUITIVE		
Medical Product Model	Nenhum Modelo/Apresentação Encontrado (a)!		
Registration	10302860125		
Process	25351.379678/2007-48		
Product Origin	FABRICANTE : INTUITIVE SURGICAL, INC – ESTADOS UNIDOS FABRICANTE : INTUITIVE SURGICAL, S. DE R.L. DE C.V – MÉXICO DISTRIBUIDOR : INTUITIVE SURGICAL, S. DE R.L. DE C.V – MÉXICO DISTRIBUIDOR : INTUITIVE SURGICAL, INC – ESTADOS UNIDOS		
Expiration Registration	17/12/2012		

Source: Anvisa (2012).

Chart 8 – List of equipment found by the term "Da Vinci"

Company Name	H STRATTNER E CIA LTDA		
CNPJ	33.250.713/0001-62	Authorization:	1030286
Product	SISTEMA CIRÚRGICO ROBÓTICO DA VINCI - INTUITIVE SURGICAL		
Medical Product Model	IS2000, IS3000		
Registration	10302860146		
Process	25351.492628/2009-83		
Product Origin	FABRICANTE: INTUITIVE SURGICAL, S. DE R.L. DE C.V - MÉXICO FABRICANTE: INTUITIVE SURGICAL, INC - ESTADOS UNIDOS DISTRIBUIDOR: INTUITIVE SURGICAL, INC. - SUÍÇA DISTRIBUIDOR: INTUITIVE SURGICAL, S. DE R.L. DE C.V - MÉXICO.		
Expiration Registration	08/03/2015		

Source: Anvisa (2012).

ANALYSIS SUMMARY

- Medical equipment does not fit into any of the technologies defined in "Ordinances No. 1101/2002 and 544/2001";
- Regarding Ordinances, it is necessary to have a defined context for the proper survey of health care coverage in the region;
- The robotic surgical system is registered ANVISA accordingly and it is indicated for the health application - prostatectomy;
  - 1 Manufacturer - Intuitive Surgical
  - 1 Supplier - H. Strattner

3.3 TECHNICAL DOMAIN

In the technical domain, the main goal is to guide the reviewer through a detailed examination of the technology, seeking to know its working principle, its main applications, its various configurations and that at the end of this analysis, the advisor will be able to compare all existing technologies and if possible highlight one that presents major technological resources, justifying them.

The da Vinci® Surgical System was initially developed for use in cardiac surgery in 1997 (MITRE; ARAP, 2008).

According to the manufacturer's website, there are three models of equipment:

- The da Vinci® standard: initial model;
- The da Vinci® S HD:
    - 3D endoscopic vision;
    - The system enables new minimally invasive options for complex surgical procedures;
- The da Vinci® Si HD:
    - Dual console;
    - Improved high definition 3D Vision;
    - An updated user interface with simplified configuration;
    - Digital extensibility.

The system is a robotic platform that enables the execution of complex surgeries with minimally invasive and is composed of three main components: the surgeon console, a patient cart and stroller vision, as Figure 3.

Figure 3 – Components of the da Vinci® Surgical System

Source: Intuitive Surgical (2007).

• SURGEON CONSOLE

The console surgeon is characterized as the control center of the system da Vinci ® robotic surgery. According Tooher (2004), the console promotes interface between the surgeon and the robotic surgical arms. It is through this that the chief surgeon interacts with surgery, through two general controllers in their hands that enable mastery of instruments and an endoscope with three-dimensional images, in addition to other commands by controllers on their feet.

The instruments referred to are named EndoWrist instruments and are of multiple use in endoscopy and should be used only in conjunction with the da Vinci ® system (INTUITIVE SURGICAL, 2007).

According to manual equipment operation, by the viewer, it is possible verify that the tools seem to be placed in the hands of the surgeon in general controllers, providing an alignment of the eye with his hands and the instruments, similarly as occurs in open surgical procedure.

The da Vinci surgical system ® was designed to translate the movements of the hand, wrist and fingers the chief surgeon in precise movements supposedly real-time surgical with instruments inside the patient. The control of the movement is brought about by of a scale and there is a reduction of tremors natural main surgeon's hand through the system. Figure 4 shows the console surgeon and positioning as the doctor during the procedure.

Figure 4 – Components of the da Vinci® Surgical System

Source: Intuitive Surgical (2012).

The constituents of the surgeon's console are: (Figure 5):

- Controllers general: enable the propagation direction and the direction of movement surgeon to control the robotic arms, instruments and endoscope within the patient. Its use is given by the index finger and thumb of the surgeon. The maneuver instruments EndoWrist occurs by adjusting the distance between the two fingers or bringing them close. To drive the robotic arms and the endoscope, the surgeon must stir and move their hands and arms. The general controllers to filter the natural noises of main surgeon's hand and avoid tremors in the surgical field (Tooher, 2004).

- Viewer Stereo: The stereo viewer provides the video image to the operator's console surgeon. This, according to Intuitive Surgical (2007), is ergonomically designed, it aims to provide a support for the head and neck of the doctor. However, the repositioning of the head surgeon does not affect the image quality. According Munz et al. (2004), the stereo viewer consists of two high-resolution monitors that display the 3D image fused device field. This would be a preview of the full screen mode. Another option is the way multiple images which makes present the 3D image of the surgical field with one or two additional images. When the endoscope is enabled, video channels left and right from the integrated stereo viewer provides the operator with continuous 3D image, so that virtually extend the operator's eyes to the surgical field. The endoscope of High Resolution, offers custom lens doubles, along with two three-chip cameras, as Figure 5 (INTUITIVE SURGICAL, 2007).

- Modules of the left and right side: The modules of the left and right sides are located in the armrest console of the surgeon. Modules are used for system configuration, through the activation functions, by the user. Are some of the access functions through the modules: connect the console surgeon, turn the stroller vision, connect the patient cart, check alignment of the endoscope, brightness / contrast, among others.

- Panel pedal: is positioned on the floor of the console surgeon and it is through the operator activates some functions necessary for using the system da Vinci, as the driver focus that aims to adjust the focus of the lens endoscope. Electrosurgical units compatible with the da Vinci ® System can be used, and when this need to select the operating mode monopolar or bipolar activation is given by the pedal.

Figure 5 – Components of the da Vinci® Surgical System: Surgeon Console

Source: Intuitive Surgical (2012).

• PATIENT - SIDE CART

The stand of the patient is the system component da Vinci ® that primarily performs the activity to support the robotic arms, where are the instruments and the endoscope, and should be located next to the surgical table.

According to information from Intuitive Surgical (2007), the system uses a technology center remote. The remote center is a fixed point in space around which the patient side cart moves, and thus enables the maneuvers of the endoscope and the instruments within the surgical field while exerting minimal force on the wall body of the patient.

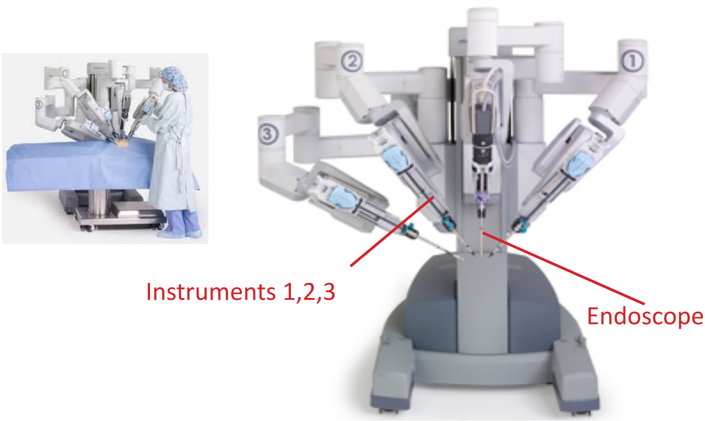
The patient side cart also needs an operator who performs the adequate exchange of the instruments, assists the main physician who is in the console surgeon and follows patients. The operator can view the operative field using a monitor. The da Vinci ® S version offers a touch-screen monitor, which occurs in both the preview image as endoscopic control various system functions (H. Strattner, 2010).

The system was designed so that the operator actions the patient´s stand are the priority actions and precede the operator console surgeon (INTUITIVE SURGICAL, 2007). Figure 6 illustrates the patient side cart. The first two arms, which represent the right and left hand of the surgeon, keep the instruments.

The third arm is an optional to extension of surgical capabilities with the addition of another instrument EndoWrist possibly minimizing the role of the physician. According to Intuitive Surgical (2007), the fourth arm is where couples the endoscope, allowing the surgeon to easily change, move, zoom and rotate your field of vision from the console.

Finally, the arms are actuated by the pedal command, located in the console surgeon, as mentioned earlier.

Figure 6 – Components of the da Vinci® Surgical System: Patient – Side Cart

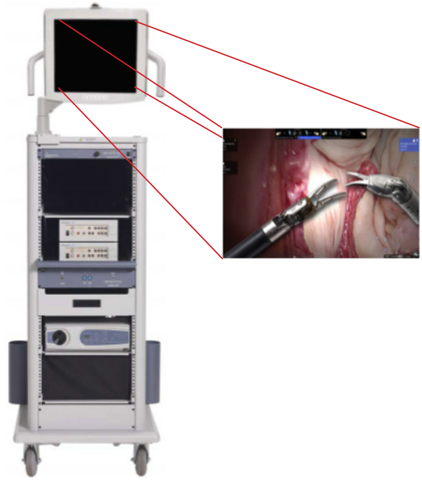


Source: Intuitive Surgical (2012).

• VISION SYSTEM

The Vision System allocates processing images equipment, perfecting the 3D images of the surgical field. This, shown in Figure 7, requires an operator, who cannot be sterilized during the procedure.

Figure 7 – Components of the da Vinci® Surgical System: Vision System



Source: Intuitive Surgical (2012).

ANALYSIS SUMMARY

- We found different models from the same manufacturer;
- Isn´t presents alternative technology for comparison;
- The system consists of three main components: the surgeon console, a patient side cart and the cart of vision system;
- The surgeon's console is the control center that promotes an interface between the surgeon and the robotic surgical arms;
- The patient side cart performs the activity to support the robotic arms, which are the instruments and the endoscope;
- The vision system allocates processing images equipment, perfecting the 3D images of the operative field.
- According to information released by the manual and the manufacturer's website and supplier, MCE attend technically the demand of the health system in relation to prostate surgeries;
- Main sources: Manuals and site of the manufacturer and supplier.

3.4 OPERATIONAL DOMAIN

This domain consists of analyzing the external and internal variables that influence the performance of the technology and the service that uses such technology. Due to covering several analysis variables this domain was subdivided into various items in an easy-to-understand manner.

- HUMAN FACTORS AND ERGONOMICS
  - The da Vinci® surgical system provides an alignment of the eyes with the hands;
  - The posture for the surgeon is adequate and comfortable;
  - Regarding the equipment positioning in the operating room:
  - The patient - side cart is motorized, therefore, its displacement is easy,
    - There is an easy coupling of the arms in the holders;
    - The monitor has a touch screen;
    - There are light indicators for status and data connections via fiber optics.
- TRAINING
  - For the appropriate use of the technology, in order to perform the procedure of Robot-Assisted Radical Prostatectomy is necessary:
    - Assembly of a specialized team with at least a surgeon, an anesthetist and an assistant
  - Scientific Literature Search

Chart 9 – Presentation of the training courses results

Study	Results
HO, C. et al. Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011 (Technology report no. 137)	Short Course: 2 – 3 days Training Centers: • It consists of lectures about engineering principles, monitoring of surgeries on live animals or cadavers by experienced surgeons; • Surgeon performs 3 training surgeries under the supervision of experienced surgeons; • The first cases a surgeon may take 6 to 8 hours each. The learning curve for performing robotic surgery can vary depending on the surgical procedure and prior experience of the surgeon; • In some cases, it is necessary about 200-250 procedures for surgeons to become so capable as with other surgical methods. • Patient selection can impact in the learning curve of the surgeon; • The patient's morphology and health state and the disease characteristics may be considered in selecting cases to less experienced surgeons to provide a positive result after the procedures/initial orientations. The manufacturer provides training to other members of the surgical team. • The staff training are more focused on the sterilization process, arrangement of operating room, interfaces between instruments and the patient side-cart and surgical equipment maintenance; There are no standards for training and credentialing in robotic surgeries. The number of trained staff depends on the expected volume of surgeries. All team members should have substitutes.

Continue

Conclusion

Study	Results
Monitoring health technology form MHT REBRATS	For the surgeon training: Course: 16 hours Preceded theoretical discussions and at least 5 surgeries; The first 20 surgeries should be performed under the supervision of a qualified instructor. Course: 48 hours Console training, followed by animal training and 6 trainings accompanied by a surgeon with proven experience in more than 15 cases. Course: 2 days Procedures performed on animals; Necessary 15-20 surgeries to obtain certification. For nursing staff: training is about 32 hours with certification. There is the need for continuing education, mainly from the surgeon's specific training and updating on new protocols.
Checklist about robotic surgery system and technical visit conducted by the IEB-UFSC 2012.	Surgeon training is held in the international laboratories (Manufacturer), for 2 days (total 16 hours) followed by 4-5 surgeries with expert supervision and reassessment every 5 surgeries. The maximum interval between surgeries must be 2 weeks. For experienced surgeons, the training is about 60 specific procedures. To become an expert surgeon is necessary 150 to 200 cases depending on the procedure.

Source: Own Elaboration.

- Learning Curve
    - Medical-care equipment classified as highly complex

Chart 10 – Learning curve results

Study	Results
Schreuder, H. W., Wolswijk, R., Zweemer, R. P., Schijven, M. P., & Verheijen, R. H. (2012). Training and learning robotic surgery, time for a more structured approach: A systematic review. BJOG: An International Journal of Obstetrics & Gynaecology, 119(2), 137-149.	Bivalacqua (2009) finds that surgeons are proficient for RS on the order of 40 cases. Samadi et. Al (2007) considers longer, on the order of 70 cases. Or YC et. al (2010) to achieve oncological results comparable to a surgeon experienced in open surgery, the learning curve is expected to be 250-400 cases. Doumerc et.al. (2010) reports that noted a "flattening" of the learning curve after 140 cases and a flattening for larger tumors after 170 cases.

Continue

Conclusion

Study	Results
Kamran Ahmed , Amel Ibrahim , Tim T. Wang , Nuzhath Khan , Ben Challacombe , Muhammed Shamim Khan and Prokar Dasgupta. Assessing the cost effectiveness of robotics in urological surgery – a systematic review. Centre for Transplantation, King's College London, King's Health Partners, Department of Urology, Guy's Hospital, London, UK. Accepted for publication 10 November 2011	Some studies indicate that the robotic approach could have a shorter learning curve. The additional costs of the robotic surgery could be compensated by improving the surgeon's formation and, thereafter, a shorter learning curve; and minimizing the initial purchasing and maintenance costs. The robotic surgery could require a shorter learning curve (20 – 40 cases), although the evidence is inconclusive. The robotic surgery provides postoperative results similar to laparoscopic, but with a shorter learning curve. A systematic review by Ficarra et al. [15] analyzed studies comparing robot-assisted prostatectomy surgery with open surgery. They discovered that the robot-assisted prostatectomy had a shorter learning curve (40 – 60 cases).

Source: Own Elaboration.

- The company has training for all staff involved: surgeon, anesthesiologist assistant, operating room technician and clinical engineer;
- The training can be performed in loco and/or International Training Centers. It is composed of didactic sessions and specialized laboratories that teach techniques preoperative, intraoperative and postoperative, exclusive to robotic system.
- Necessary a continuous qualification program in order to keep the learning curve of the medical care equipment.
- Site for training and support of the Robotic System:

Figure 7 – Site Training Online

Source: da Vinci (2012).

• INFRASTRUCTURE: Installations and Physical Space

- Air Conditioning System (Conditioned environment);
- AC Sockets dedicated to the 3 main components, without noise and with a ground wire.
- Network Cabling: points for internet access or network access via wireless.
- Environmental Conditions (Chart 11):

Chart 11 – Environmental Conditions

Environmental conditions for operation:	Temperature: 10 – 35 ºC / 50 – 95 ºF; Humidity: 10 to 85 % non-condensing; Pressure: 645 mm Hg to 795 mm Hg.
Environmental conditions for storage and transportation:	Temperature: 10 – 50 ºC / 50 – 122 ºF; Humidity: 5 to 95 % non-condensing transportation and 10 to 85 % non-condensing storage.

Source: Intuitive Surgical (2012).

- Electrical installations (Chart 12):

Chart 12 – Electrical installations

Voltage	Current	Frequency
230V CA	50/60Hz	6A
100/115V CA	50/60Hz	12A

Source: Intuitive Surgical (2012).

- Scientific Literature Search:

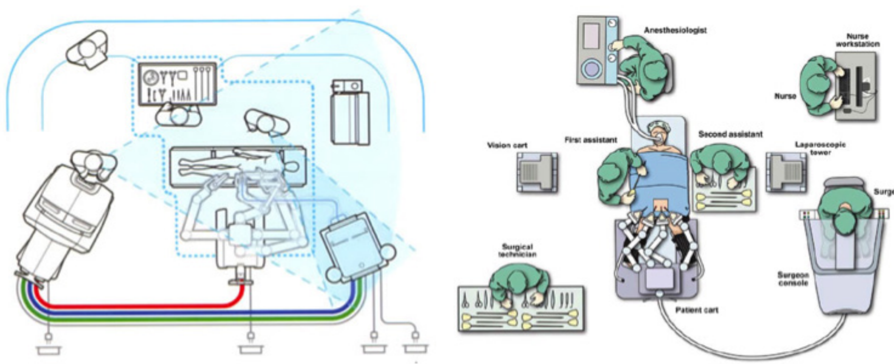
Chart 13 – Infrastructure results

Study	Results
HO, C. et al. Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011 (Technology report no. 137)	Minogue Medical Inc.: • Minimum physical space = 37,16m² • à 03 electrical outlets dedicated - 115V/20A Steers et al.: • Minimum physical space = 52,2 m² • à Room dedicated to robotic surgery to avoid the Palmer et al.: • Minimum physical space = 65 m² to 67 m²
Monitoring health technology form MHT REBRATS	Surgery room with enough space to accommodate all system elements, anesthesia machine and auxiliary table for instrumental: 40 m² - 48 m². Computer network – Internet connection with free access to remote da Vinci® Onsite 4 110V electrical outlets with independent 20 A circuit. Vision System: A connection in a different circuit from the rest of the system is recommended, in order to avoid possible interferences and image quality loss.
Checklist about robotic surgery system and technical visit conducted by the IEB-UFSC. 2012	• Minimum physical space = 42m²; • “Good” physical space = 50m²; • “Great” physical space = 72m². • Identified between 42m² - 52m². • Manufacturer recommends = 48m² • Electrical installations independent; • Internet connection.

Source: Own Elaboration.

- Operating Room Setup:

Figure 8 – Schematic of operating room setup and surgical team for the da Vinci®



Source: da Vinci (2012) and H.Strattner (2012).

• ACCESSORIES, STORAGE

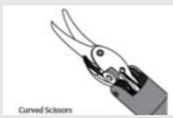
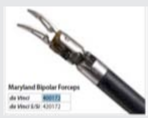
- Key accessories:
    - Forceps, tweezers, optical, cables and sterile instrument arm adapter;
    - The instruments are identified by colors, diameters and types and their life cycle depends on their identification and each instrument has a counting use system.

Figure 9 – Instruments and Accessories

Source: Intuitive Surgical (2012).

- Accessories and instruments recommended minimum procedure for radical prostatectomy

Chart 14 – Accessories Robotic Surgery System

2 *Large Needle Driver*	 
1 *ProGrasp Forceps*	
1Hot Shears Scissors	 
1 *Maryland Bipolar Forceps*	 

Continue

Conclusion

3 *Cannula Seal*	
1 *Tip Cover Accessories*	
3 *Drape*, *Instrument Arm* 1 *Drape*, *Camera Arm* (*For use with Camera Cannula Mounts*) 1 *Drape*, *Camera*	
Others	

Source: Intuitive Surgical (2012).

Due to a sterilization process for specialized forceps, it is necessary to acquire a specific ultrasonic washer (Cleansing Equipment by Thermal disinfection/ultrasound) specific with pressurized fluid injection into the forceps lumen.

Figure 10 – Example Ultrasonic Washer

Source: H. STRATTNER & CIA LTDA (2013).

STORAGE:

- Specialized storage is not needed for the medical equipment or for the accessories and materials. Standard storage procedures should be used.
- The instruments and accessories should be stored in a clean, dry and well ventilated environment.
- The storages indicated in the situation below could cause the occurrence of damages or constitute an infection control risk.
- Direct sun light exposure, high temperatures or high humidity.
- X-ray exposure, radioactive rays or high electromagnetic waves (such as near of a microwaves therapeutic device, MRI, wireless set, etc.).
- Store the instrument in its original package.
- When transportation or storage is necessary, the instruments and the patient cart camera must be removed and the joints bent inward towards the center column.

MAINTENANCE

- Preventive maintenance of the robotic surgery system is performed by an authorized representative of the manufacturer (performed at least every 3 months);
- The system main components don't have any parts in which the operator could perform assistance tasks, except the system accessories (endoscope, endoscope sterile adapter, camera arm sterile adapter and hold to cloths) and the illuminator.
- If the system requires corrective maintenance or assistance, technical support must be called. The minimum guarantee provided by the company is 1 year, all expenses are covered by the maintenance contract: including parts, displacements, visits, among others, excluding case of misuse, if proven;
- The maintenance service is provided by an authorized company by manufacturer (retailer and technical equipment representative in Brazil). In case of failure, it can be solved by Clinical Engineer of the Hospital, based on the guidelines of the national representative, in cases that require a more specialized maintenance and when the Clinical Engineer can't solve the problem, the national company must be called. If the national company can't solve it, it may be necessary to get in touch with the international company;
- It was found that the robotic system constantly sends data about its operation through TCP/IP network. Therefore, the national company representative can identify possible failures and send a support, if necessary (Remote monitoring equipment operation - Online system with international company)

SUSTAINABILITY

- Accessories are discarded as medical waste by hospitals.

ANALYSIS SUMMARY

- Scanty scientific evidence for operational domain
- Infrastructure specific to installing the equipment
- The evidence shows that there is a need for an ongoing training program to maintain the learning curve of the medical equipment.
- Maintenance specialist.

3.5 DOMAIN ECONOMIC

This domain intends to conceptualize the advisor about the various types of existing economic evaluations applicable in the health field, which according to the needs and perspective can then choose the most suitable one.

- Economic Evaluation Studies
    - Scientific Literature Search
        - Average Costs per Procedure

Estimates (see Chart 15) were made based on a literature review conducted by the Canadian Agency for Drugs and Technologies in Health. An average of 130 procedures per year and a lifetime of seven to robotic equipment.

Chart 15 – Average costs per procedure comparing Robot-Assisted Radical Prostatectomy (RS) and Open Radical Prostatectomy (OS)

Costs	OS	RS	Difference
Medical equipment and accessories	$ 3 785	$ 0*	$ 3.785
Single-use supplies	$ 2 542	$ 212	$ 2.330
Course for system operation	$ 36	$ 0	$ 36
Maintenance contract	$ 1 064	$ 0	$ 1.064
Hospital stay	$ 6 279	$ 9.993	$ -3.714
Fees	$ 1 381	$ 1.022	$ 395
Anesthesia	$ 581	$ 470	$ 111
Transfusion	$ 12	$ 125	$ -113
TOTAL	$ 15.680	$ 11.822	$ 3.858

Source: HO, C. et al., 2011.

- Cost Utility and Cost Effectiveness Analysis:

Chart 16 – Results HTA Reports – QALY

Study	Type of Study/ Population	Results
Ollendorf et al (2009)	Increment of 0.16 QALY and $ 1,740.00/QALY for RS versus OS.	Systematic Review of case series
O'Malley and Jordan (2007)	Increment of 0.093 QALY and $ 24,475.43/QALY for RS versus OS.	Observational study. n= 100 – OS n= 500 – RS
Hohwü et al (2011)	Increment of 64.34 Euros for RS versus OS. 7% of effectiveness in favor of RS.	Cohort study N=231 (men, 50-69 years) Values of treatments considered successful

Source: Own Elaboration.

- Total Cost Of Ownership (TCO):

Chart 17 – Total Cost of Ownership Results

Costs	Basis of the Estimate	Estimated Value ($*)	Time (years)	Total Estimated ($) (20/03/2012)
Acquisition	Market research	2,726,281.00	-	2,726,281.00
Planning	5% of acquisition value	136,314.00	-	136,314.00
Installation	Market research	27,262.00	-	27,262.00
Maintenance	Market research	120,000.00 year (after the guaranty)	6	720,000.00
Operating	Market research	3,259.67 (supplies and human resource for procedure) X 300 year	7	6,845,307.00
Training	Market research	6,543.00 year	6	39,258.00
Replacement	Acquisition value plus the IGPI (last 12 months – March 2012)	2,726,281.00 + 3.32%	7	3,426,584.13
TCO				13,921,006.13

Source: Own Elaboration.

ANALYSIS SUMMARY

- Studies retrieved in the systematic review, in general, have estimated costs considering values of equipment, maintenance costs, surgeon payments, input costs and hospital stay.
- Some studies included in the systematic review did not clearly show the basis for the estimates.
- However, the selected studies, even in the presence of heterogeneous characteristics are able to point out cost trends regarding robot-assisted prostatectomy as superior to others.

4 RECOMMENDATION AND LIMITATIONS OF ANALYSIS

- This methodological guideline does not have an established flow, thereby the assessment can be started at any aspect. About the da Vinci® Surgical System, its high complexity, visits in loco were necessary;

- Evidences
    - The evidences predominate the clinical domain, which prevent the technical comparison between other equipment;
    - Evidence of case reports and expert opinions were found.

- Difficulties:
    - New technology on the market;
    - Analyze the admissibility: Ordinance No. 1101/2002 and 544/2011;
    - Analyze the operational Domain – Sustainability;
    - Get the market costs in Brazil;
    - Analyze the medical equipment from the perspective of the Health Industrial Complex;

- An economic evaluation with the Ministry of Health's methodological guideline was not performed due to a lack of specialists in the area.

5 FINAL CONSIDERATIONS

The case study had the objective of verifying problems regarding the use of the methodology, to summarize the information and evidence that allow the formulation of recommendations, in this manner, to support in the decision-making relevant the incorporation process of medical equipment in health care establishments.

Concerning technical and operational information, these should be generated and spread in a systematic manner in order to supply the assessment and formulation of recommendations.

In the validation step of the guideline, it was observed that some aspects, the evidence and information of medical equipment were thin and inconclusive. In particular, the scientific evidence was derived from observational studies that implying the development of new health policies enhance the production of scientific evidence of medical equipment, prioritizing the effectiveness. Thus, the recommendations could be transfered to other populations.

The economic analysis permits for the identification of the main components to be considered in the process of incorporating the robotic surgery system. The TCO represents a challenge in this process because there are some barriers to obtaining values to be computed. However, it is a tool to support the best technological alternatives; taking into account the diverse costs over the technology´s lifetime. Two direct contributions to the TCO may be considered: the first is to compare costs between models of competing technologies, and the second is to provide information to managers and policy-makers to predict the impact on the budget.

The economic evaluation through the Cost Utility and Cost Effectiveness Analysis offers indicators that make it possible to verify evidence that justifies costs before the benefits brought by the implementation of the medical equipment. In addition, it is possible to compare technological alternatives and identify the most cost-effective option. However, it should be understood that sometimes the design of the primary studies can produce biases in the results, thus, an intense evaluation must be performed.

The guideline identifies the possible need to establish a management strategy that allows for evidence and information production in such a way that these are disseminated and retrieved in the future of medical care equipment development.

BIBLIOGRAPHICAL REFERENCES

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. **Consulta Banco de Dados**: Produtos para Saúde, 2012. Disponível em: <http://www.anvisa.gov.br/scriptsweb/Tecnovigilancia/ResultadoGGTPS.asp>. Acesso em: 13 outubro de 2013.

BARRY, M. J. et al. Adverse effects of robotic-assisted laparoscopic versus open retropubic radical prostatectomy among a nationwide random sample of medicare-age men. **Journal of clinical oncology : official journal of the American Society of Clinical Oncology**, v. 30, p. 513-518, 2012.

GAINSBURG, D. M. et al. Intraoperative management of robotic-assisted versus open radical prostatectomy. **Journal of the Society of Laparoendoscopic Surgeons**, v. 14, p. 1-5, 2010.

GONZALEZ, P. J. A. et al. Evolución de la cirugía abierta versus laparoscópica/robótica: 10 años de câmbios em Urología. **Actas Urológicas Españolas**, v. 34, n. 3, p. 223-231, 2010.

H. STRATTNER & CIA LTDA. **Sistema Robótico da Vinci® S HD**: Lavadoras. Disponível em: < http://www.strattner.com.br/prod_medisafe_lavadoras.htm >. Acesso em: 13 outubro de 2013.

H. STRATTNER & CIA LTDA. **Sistema Robótico da Vinci S HD**. Disponível em: <http://www.strattner.com.br/prod_intuitive_davinci.htm>. Acesso em: 24 maio 2012.

HO, C. et al. **Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery**: Clinical Effectiveness and Economic Analyses [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011 (Technology report no. 137). Disponível em: <http://www.cadth.ca/en/products/health-technology-assessment/publication/2682>. Acesso em: 20 abril 2012.

INTUITIVE SURGICAL. **Manual de Instrução de Uso da Vinci® S**: Sistema Endoscópico Robótico da Vinci – Intuitive, Modelo IS2000. Intuitive Surgical.2007, 246p.

INTUITIVE SURGICAL. **EndoWrist, 2005**. Disponível em: <http://www.intuitivesurgical.com/products/instruments/>. Acesso em: 20 maio 2012a.

______. **Products**: da Vinci Surgical System. Disponível em: <http://www.intuitivesurgical.com/products/davinci_surgicalsystem/index.aspx>. Acesso em: 22 maio 2012b.

______; DA VINCI SURGERY. **Features**. Disponível em: <http://www.davincisurgery.com/davinci-surgery/davinci-surgical-system/features.html>. Acesso em: 22 maio 2012.

LALLAS, C. D. et al. Comparison of lymph node yield in robotassisted laparoscopic prostatectomy with that in open radical retropubic prostatectomy. **B J U International,** v. 107, p. 1136-1140, 2010.

LÓPES, S. E. et al. **Robótica en el tratamiento de tumores**: eficacia, seguridad e impacto económico de equipos de ultrasonidos de alta intensidad (HIFU-ExAblate). Madrid: Plan Nacional para el SNS del MSC. Unidad de Evaluación de Tecnologías Sanitarias, Agencia Laín Entralgo; 2008 (Informes de Evaluación de Tecnologías Sanitarias: UETS Nº 2006/09).

MARTÍNEZ2. M. et al. **Efectividad, seguridad e indicaciones del equipo quirúrgico Da Vinci**: Effectiveness, Safety and Indications of Da Vinci Surgical System. Madrid : Unidad de Evaluación de Tecnologías Sanitarias, Agencia Laín Entralgo, 2009. 324 p.

MITRE, Anuar Ibrahim; ARAP, Marco Antonio. Perspectivas da cirurgia robótica. **Boletim do NAU**, São Paulo, maio/jun. 2008.

MUNZ; Y, et al. The benefits of stereoscopic vision in robotic-assisted performance on bench models. **Surgical Endoscopy**, New York, p. 611-616, 2004.

PARK, J. W. et al. Comparative Assessment of a Single Surgeon's Series of Laparoscopic Radical Prostatectomy: Conventional Versus Robot-Assisted. **Journal of Endourology**, v. 25, n. 4, p. 597-602, abr. 2011.

TOOHER, R, Pham, C. **The da Vinci surgical robotics system**: Technology overview ASERNIP-S Report No. 45. Adelaide, South Australia: ASERNIP-S, jul. 2004.

YU, H. et al. Use, costs and comparative effectiveness of robotic assisted, laparoscopic and open urological surgery. **The Journal of Urology**, v. 187, p. 1392-1399, abr. 2012.

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