Rev. Salud pública. 7 (2): 166-179, 2005

Cost effectiveness of Diagnostic Laparoscopy in Reproductive Aged Females Suffering from Non-specific Acute Low Abdominal Pain

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Recibido 31 Enero 2005/ Enviado para Modificación 25 Febrero 2005/Aceptado 8 Junio 2005

ABSTRACT

Objective To compare the costs and effectiveness of early laparoscopy with those of conventional diagnostic methods based on clinical and paraclinical observation and diagnostic images for ascertaining the cause of non-specific acute low abdominal pain (NSALAP) in females of reproductive age from the third-party payers' (TPP) point of view.

Methods Population: 110 reproductive aged females suffering from NSALAP. Place: Instituto Materno Infantil, perinatal and maternal attention referral hospital in Bogotá, Colombia. Research design: cost-effectiveness study of a controlled clinical trial carried out in 1998 and 1999. Outcomes to be measured: effectiveness, direct medical costs (in Colombian pesos and their equivalent in US dollars (USD-December 2004) from length of hospital stay, diagnostic procedures carried out, medical visits and managing complications. Analysis: Cost-effectiveness incremental ratio, analysing sensitivity in five different scenarios.

Results Early diagnostic laparoscopy was more cost-effective in 4 out of the 5 possible scenarios. Savings varying from $21.875 to $69.834 (USD 9.42 and USD 30.1) were made per unit of increased effectiveness.

Conclusion Early diagnostic laparoscopy was cost-effective in 4 out of 5 scenarios dealing with managing NSALAP in reproductive aged females.

Key Words: Cost effectiveness, cost analysis, pelvic pain, laparoscopy, women's health (*source: DeCS, NLM*).

RESUMEN

Costo efectividad del diagnóstico por laparoscopia del dolor abdominal bajo agudo inespecífico, en mujeres en edad reproductiva

Objetivo Comparar los costos y la efectividad entre la laparoscopia temprana y el método diagnostico convencional basado en la observación clínica y paraclínica, e imágenes diagnósticas, para aclarar la causa del dolor abdominal bajo agudo no específico (DABNE), en mujeres en edad reproductiva, desde el punto de vista del tercer pagador.
Métodos Población: 110 mujeres en edad reproductiva con DABNE atendidas en el Instituto Materno Infantil, hospital de referencia de atención materno perinatal ubicado en Bogotá, Colombia; Diseño: Estudio costo efectividad realizado sobre un Experimento clínico controlado realizado entre 1998 y 1999; Se evaluaron: la efectividad, costos médicos directos (en pesos colombianos y su equivalente en dólares americanos -USD-, a diciembre de 2004) dados por estancia hospitalaria, procedimientos diagnósticos realizados, visitas médicas, y manejo de las complicaciones. Se determinó la razón incremental de costo-efectividad, y se hizo análisis de sensibilidad en cinco escenarios diferentes.
Resultados La laparoscopia diagnóstica temprana es mas costo efectiva en cuatro de cinco escenarios posibles. Por cada unidad de efectividad incrementada se produce un ahorro que varía entre $21 875 y $69 834 (USD 9,42 y USD 30,1).
Conclusión La laparoscopia diagnóstica temprana es costo efectiva en 4 de 5 escenarios en el manejo del DABNE en mujeres en edad reproductiva.

Palabras Clave: Efectividad, costo y análisis de costo, dolor pélvico, laparoscopia, salud de las mujeres (*fuente: DeCS, BIREME*).

Acute low abdominal pain is a common reason for reproductive aged females to become hospitalised. 67 % of patients suffering from acute abdominal pain present non-specific clinical pictures, this being much more frequent in females (1). A conventional diagnostic approach for determining the cause of pain is based on clinical observation, laboratory tests and diagnostic images (2-6). An alternative approach uses early laparoscopy for making a visual diagnosis of the abdominal-pelvic cavity in an attempt to identify the affected organ (2, 7-9). A situation thus occurs where it becomes necessary to compare two competing diagnostic technologies, understood as such because they are used for the same purpose and are mutually exclusive in the same patient (10), neither one having been shown to be superior over the other in our setting (11).

Each method's effectiveness has to be evaluated when making this comparison; the number of relevant diagnoses, the associated complications and the costs associated with each method must be evaluated. These must be born in mind by society in general, institutions and third-party payers (TPP) since they must become more efficient in handling the scare resources available (12) and provide better quality attention. Laparoscopy represents a case of special attention due to the technique's great spread which has not always been preceded by suitable evaluation.

Our purpose was to carry out an economic analysis from the TPP point of view by comparing both methods' diagnostics costs and effectiveness in terms of dealing with the health of patients suffering from non-specific low acute abdominal (NSALAP), since this investment could lead to greater costs, having equal or less effectiveness, or reduce costs and improve effectiveness.

METHODS

A randomised clinical trial was carried out in the Instituto Materno Infantil between November 1997 and February 2000 for comparing the effectiveness of early laparoscopy (new procedure) and the conventional diagnostic method (standard procedure) in females suffering from NSALAP. This is a referral hospital dealing with maternal, perinatal and gynaecological entities (11).

The costs incurred by both methods in reaching a diagnosis were considered from the TPP point of view. TPP have an important influence on prices paid to health institutions for surgical procedures in the health market in Colombia.

Direct medical costs before diagnosis was made were taken in to account. All costs were related to clarifying the cause of pain. Intra-hospital procedures for making a diagnosis or providing treatment for complications were considered as well as the length of stay associated with them and treatment received which was considered to be unnecessary as it had been based on an erroneous initial diagnosis. The costs of tests which are not routinely used in studying the cause of pain such as endometry biopsy, cervical or endometry cultures were not included, nor were base entity surgical or medical treatment or direct non-medical costs (transport, etc). The number of therapeutic procedures which could be done by laparoscopy avoiding interventions which used to be done by laparotomy was taken into account as being added value. Data were taken from the case report format especially designed for

the study and the clinical history. They were estimated from the tariffs for paying the obligatory traffic accident insurance (SOAT). Its tariffs have been homologated for paying for services contracted by the local health entity (Secretaria Distrital de Salud de Bogotá).

The costs at constant prices for 2004 were calculated on tariffs for 1998, adjustments being made for increased consumer price indices for 1998 to 2003 in the following way: a 16,7 % increase in 1998, 9,2 % for 1999, 8,7 % for 2000, 7,6 % for 2001, 6,9 % for 2002 and 6,4 % for 2003. The consumer price index is the basis for readjusting SOAT tariffs in Colombia. A value of 20 % per year was taken for calculating depreciation of equipment. No discount was applied since both diagnostic methods were applied for a short period of time, meaning that the effect of neither could be fully ascertained.

The data for constructing the scenarios when analysing sensitivity were obtained from the available medical literature in relation to length of say, number of diagnostic exams and complications. Expert opinion was consulted when information could not be obtained for the test.

The representative market rate on December 20th 2004 was taken for estimating the cost in US dollars (i.e. $2 320 Colombian pesos per US dollar).

Defining the terms: Non-specific low abdominal pain: pain about which two observers disagree regarding base diagnosis following six hours' observation or which does not follow a particular disease's classical course; Conventional diagnostic method (standard procedure): diagnosis based on clinical evaluation and diagnostic tests done in parallel or sequentially, the patient being strictly observed. This could include surgical interventions such as precision laparotomy; Laparoscopic method (new procedure): diagnosis based on visualising the abdominal-pelvic cavity and structures contained there, done immediately after the first 6 hours from being admitted and during the first 24 hours of being hospitalised; Diagnostic effectiveness: a method's ability to make an exact diagnosis of a particular disease; Analysis of sensitivity*:* a strategy used for evaluating the stability of conclusions drawn from analysis when some of the variables (costs, discount rate) change; Scenario: different suppositions constructed for analysing sensitivity (13) using extreme values for a particular variable, obtained from the literature or experts' consensus for evaluating conclusions' stability; Intention to diagnose*:* analysing the effectiveness of a diagnosis carried out according to patients' initial assignation and taking a particular institution's conditions of daily life into account; Medical direct costs: Hospitalisation costs, Operating room costs for laparoscopy and laparotomy, laboratory costs and those

for images and other diagnostic interventions, taking into account the amount paid for lab tests, costs regarding complications.

Indirect or direct non-medical costs such as transport and incapacity were not taken indo account since TPPs do not assume responsibility for paying them in this particular case. Given that only costs for establishing the diagnosis were included, then those produced by treating the base non-complicated entity were not included nor when a complication was present during the first 24 hours of hospitalisation.

Analysis

The costs above mentioned were taken into account for calculating individual cost (for both the new and standard procedures). 1998 was taken as the base year for estimating costs and effectiveness. Total mean cost per patient and per group was estimated for analysing cost effectiveness.

Mann Whitney U test was used for comparing the costs in each group, given the tendency of data to have an abnormal distribution (14). Intention to diagnose analysis assuming costs of laparotomy in the standard procedure group, even though some patients were subjected to the new procedure for ethical reasons (12).

Cost effectiveness was analysed by cost-effectiveness incremental ratio, obtained by comparing costs/natural outcomes between the groups as follows (15):

$$R_{C/E} = \frac{Cn - Cc}{En - Ec}$$

Where C_n: new procedure costs, C_c: standard procedure costs.
E_n: new procedure effectiveness, E_c: standard procedure effectiveness.

Incremental cost analysis presented the increase in costs for each increase in effectiveness (15).

Analysis of sensitivity: The two actual scenarios were compared, also the best and worst scenarios for both methods and , the best scenario for the standard procedure compared to the worst scenario for the new procedure and vice versa.

The sensitivity of the effectiveness of both methods was analysed according to the best and worst published scenarios. STATA (version 8.1) software was used for statistical analysis.

RESULTS

110 females suffering from non-specific acute low abdominal pain were admitted between November 1997 and February 2000. Table 1 shows patients' base characteristics and final diagnosis.Laparoscopy provided 82 % correct diagnoses; standard procedure was 78 % effective (11).

Table 2 shows the distribution of resources used for achieving a final diagnosis. Length of stay needed the greatest amount of resources, the greatest number of medical visits and the greatest number of haemograms and ecographies were requested for the standard procedure group.

Sensitivity Analysis: The best scenario when analysing cost sensitivity for the standard procedure was considered to be a one-day stay, just base exams being done and that there was no complication requiring laparotomy or uterine curettage. The series having the least number of entities presenting NSALAP revealed a series of 41 patients, having unexplained abdominal pain, 5 % of them requiring surgery (16).

The worst scenario for the standard procedure considered a 4,1 day-stay for patients having non-specific abdominal pain described in a series of 100 patients (1) Regarding laboratory tests or diagnostic images, it was assumed that three haemograms, two uroanalyses, two qualitative pregnancy tests and two pelvic and transvaginal ecographies would be requested for the longest stay.

The greatest numbers of patients possibly requiring surgery were found ranging from 41 %, in a series of 100 cases of patients having suspected appendicitis or gynaecological pathology, surgery was performed on 41 patients (17), to 62 % in a series of 119 patients suffering from acute abdominal pain studied (18). The frequency given by the former publication was chosen as its population was similar that being studied here.

Regarding complications, a 10 % frequency in delay was determined for establishing secondary complications as being the cause of pain. This figure was obtained by considering a 6 % frequency of perforated appendicitis. The foregoing must be added to 1,5 % of patients having ectopic pregnancy

could present complications and 2,5 % of patients having slight EPI could present secondary complications when diagnosis is delayed. Such a figure is similar to that referred to by Nevez in patients suffering from acute abdominal pain (19). An average of two days' prolonged hospital stay was estimated and that 4 out of each 5 patients having complications would require open surgery for treating their complications.

The best scenario for the laparoscopic method considered that there would be no hospitalisation costs because a patient is treated as an outpatient, bearing in mind that a patient presenting a gynaecological pathology can be handled as an outpatient. Only initial exams would be done, no complications would arise and that up to 85 % of major surgery could be avoided if operation laparoscopy were done immediately.

Table 1. Base characteristics and final diagnosis in 110 females suffering from non-specific pain in the Instituto Materno Infantil - Bogotá, Colombia

Characteristic	Group 1 Standard procedure	Group 2 New procedure
Age	30,2 ± 6,7	27,6 ±6,7
Time spent suffering pain (days)	4 (1-80) 9,5 ± 13,8	3 (1-60) 9,2 ±15,1
Maximum temperature (^{o}C)	36,5 ± 0,9	36,7 ±0,5
Leukocytes	10 253 ± 4 029	8 771 ± 3 418
Haemoglobin (gr. / %)	13,0 ± 1,5	12,7±1,7
Time before diagnosis was made (days) Conclusive diagnosis	±2,32 1 (1-12)	1,30 ± 0,.72 ** 1 (1-5)
Pelvic inflammatory Disease	37	23
Appendicitis	1	1
Ectopic pregnancy	5	5
Ovarian Cysts	4	11
Endometriosis	3	5
Healthy pelvis	0	4
Urinary infection	2	0
Uterine perforation	1	0
Retrograde menstruation	0	2
Pelvic varicocele	0	1
Undiagnosed patients	2	3

For constructing the new procedure's worst scenario.was obtained by considering a two-day stay for post-operation care taken from a study published on a series of 19 patients (20). A 10 % complication frequency reported (19), with 20 % laparotomy frequency was considered, since laparoscopy did not provide sufficient information (21), without which major surgery could be avoided due to technical limitations, particular norms applying to a particular service and the low frequency of a pathology requiring therapeutic surgical procedures. Regarding complications, it was considered that all patients presenting serious complications would require laparotomy for completing the procedure and examining the cavity for discarding vascular or visceral complications. It was also considered that hospitalisation would be prolonged by two days for managing such complication.

Table 2. Length of stay, medical visits and laboratory exams according to diagnostic method in patients suffering non-chronic pelvic pain in the Instituto Materno Infantil - Bogota, Colombia

Outcome		Group 1 Standard procedure n=55	Group 2 New procedure n=55	P
Length of stay before diagnosis (days)		2.3 ± 0.31	1.4± 0.14	0.009*
1 day		31 (56)	43 (78)	
2 days		10 (18)	7 (13)	
3 days		4 (7)	3 (5)	
4 days or more		10 (18)	2 (4)	
Number of medical visits		5 (1-24)	3 (1-14)	0.0001**
Number of haemograms		1 (1-4)	1 (1-2)	0.0007**
	1	37 (68)	51 (93)	
	2	13 (24)	4 (7)	
	3	5 (8)	0	
Number of uroanalysis		1 (1-3)	1 (1-2)	0.035**
	1	45 (82)	52 (95)	
	2	7 (13)	3 (5)	
	3	3 (5)	0	
Number of pregnancy tests		1 (1-2)	1 (1-1)	0.070**
Number of pelvic ecographies		1 (1-3)	1 (1-1)	0.0003**

Mean ± standard deviation; Number (%); Median (range); * T-Student test was used for normal distribution variables; ** Mann Whitney U test was used for abnormal distribution variables. Significance level: 0.01; Number of patients related to outcome (percentage)

Tables 3a and 3b shows hospital costs in Colombian pesos and US dollars (US$) for each procedure related to average stay, lab test and pelvic ultrasounds used in each method, the number of surgical interventions carried out in each group and procedures avoided, as well as the number of procedures

in the best and worst scenarios. Total average costs per patient in each group were obtained from this data.

Overall comparison of costs between both methods revealed no statistically significant differences in the real scenario (p=0, 74 Mann Whitney U test); however, lower hospital costs were observed in the group of patients submitted to laparoscopy. The cost-effectiveness incremental ratio, of the two methods being studied was analysed in the different scenarios, taking the foregoing information into account.

Scenario 1: actual scenario, data obtained from the study.

$$\frac{\$364.176 - \$467.346}{82\% - 78\%} = \frac{-103.169(US\$ - 44.47)}{+4\%}$$

Laparoscopy would be less expensive and more effective. The TPP would save $25 792 per patient (USD 11,1) for each unit of diagnostic effectiveness increasing with laparoscopy.

Scenario 2: the best scenario for both methods:

$$\frac{\$32.063 - \$241.567}{91\% - 88\%} = \frac{-\$209.503(US\$ - 90.3)}{+3\%}$$

Laparoscopy would be less expensive and more effective. The TPP would save $ 69 834 ($USD 30,1) for each unit of diagnostic effectiveness increasing with laparoscopy.

Scenario 3: the worst scenario for both methods:

$$\frac{\$598.528 - \$992.283}{78\% - 60\%} = \frac{-\$393.754(US\$ - 169,7)}{+18\%}$$

Laparoscopy would be less expensive and more effective. The TPP would save $ 21 875 (US$ 9,4) by using laparoscopy for checking a diagnosis, per increase in each unit of effectiveness.

Scenario 4: the best scenario for new procedure *cf* worst standard procedure scenario:

$$\frac{\$32.063 - \$992.283}{92\% - 60\%} = \frac{-\$960.219(US\$ - 413{,}8)}{+32\%}$$

Laparoscopy would be less expensive and more effective. The TPP would save $30 006 (US$ 12,9) by using laparoscopy for checking a diagnosis, for each increased unit of effectiveness.

Scenario 5: worst new procedure scenario *cf* best standard procedure scenario:

$$\frac{\$598.528 - \$241.567}{78\% - 88\%} = \frac{+\$356.951(US\$ + 153{,}8)}{-10\%}$$

Laparoscopy would be more costly and less effective.. The hospital would have been paid $35 696 (USD 15,3) more for each unit of reduced effectiveness in this situation.

The new procedure would be more cost-effective than the standard procedure for patients suffering from NSALAP in two scenarios. This was equally effective in two scenarios but led to minimising costs in the study of patients suffering NSALAP. The new procedure was not cost-effective in one scenario since it reduced effectiveness at greater cost.

DISCUSSION

The economic study of implementing programmes for attention, diagnosis or therapeutic intervention has become a current need given health systems' limited resources whether provided by government or private agencies.

This type of approach provides another tool for evaluating the performance of strategic alternatives, especially when they are mutually exclusive since applying one method doe not allow the other to be applied, as is the case when applying early endoscopic diagnostic technology.

Diagnostic technologies could be evaluated from the point of view of their diagnostic validity (sensitivity and specificity), reliability (intra- or inter-observer agreement) and effectiveness, understood as being the suitable use of an intervention according to a specific situation (22). In this case, it would be a technology's performance for diagnostic use and the cost effec-

tiveness or analysis of the cost of implementing this new technology related to the increase in expected or acceptable minimum exactitude given this new application of technology.

Table 3a. Real estimation of costs for different procedures according to the standard diagnostic method, used in a series of 110 patients suffering from non-specific low abdominal pain in the Instituto Materno Infantil-Bogota, Colombia

Standard method (conventional) n=55							
			Scenario ($Col)			Scenario ($US)	
Procedure	Unit value ($Col)	Real estimation	Worst	Best	Real cost ($US)	Worst	Best
Day hospitalisation (n)	176 595	2,3	4,1	1	9 629	17 165	4 187
Haemogram (n)	2 855	1,4	3,0	1	95	203	68
Uroanalysis (n)	2 669	1,2	3,0	1	75	190	63
Qualitative pregnancy test (n)	2 608	1,1	2,0	1	69	124	62
Pelvic and transvaginal ecography (n)	38 955	1,2	2,0	1	1 127	1 847	924
Diagnostic laparotomy (n)	327 864	22/55	23/55	3/55	57	3 250	424
Complications (n)	-	0/55	5/55	0/55	-	718	-
Obstetric curettage (n)	64 299	1/55	1./55	0/55	28	28	-
Total cost	615 846				11 079	23 524	5 727
Cost per patient					201	428	104

Cost-effectiveness studies can be based on information obtained from revising the literature for constructing some theoretical scenarios or based on controlled clinical trials (CCT) evaluating the effectiveness provided by data emerging from the real scenario of daily life in the area of work and resort to secondary sources of information in the literature for assembling the best and worst scenarios in which the technology to be evaluated is to be analysed (13). The methodology based on CCT is used in this study, providing greater validity for the estimates made.

Their application is limited since diagnostic evaluation methods depend on institutional protocols and the tacit knowledge at hospitals' disposal, known as "the medical school", meaning that this could vary the number of exams requested. Other factors limiting results being generalised are the curve of experience, the degree of available technological development and the value of services which are contracted by TPPs.

However, contracted services can be calculated from tariffs recognised by each TPP in each institution, based on information provided regarding aspects such as the number of procedures carried out, days being hospitalised and medical visits required. They do allow modifications to be introduced to best and worst performance scenarios, given the characteristics common to an institution with which it is wished to contract.

Table 3b. Real estimation of costs for different procedures according for Laparoscopic diagnostic method, used in a series of 110 patients suffering from non-specific low abdominal pain in the Instituto Materno Infantil-Bogotá, Colombia

Laparoscopic method (new) n=55							
			Scenario ($ Col)			Scenario ($ US)	
Procedure	Unit value ($ Col)	Real estimation	Worst	Best	Real cost ($ US)	Worst	Best
Day hospitalisation (n)	176 595	1,4	2	-	5 861	8373	-
Haemogram (n)	2 855	1,0	1	1	68	68	68
Urinalysis (n)	2 669	1,0	1	1	63	63	63
Qualitative pregnancy test (n)	2 608	1,0	1	1	62	62	62
Pelvic and transvaginal ecography (n)	38 955	1,0	1	1	924	924	924
Diagnostic laparotomy (n)	327 864	3/55	11/55	0/55	424	1 555	-
Diagnostic laparoscopy (n)	96 449	55/55	55/55	55/55	2 287	2,287	2 287
Complications	-	1/55	5/55	0/55	217	859	-
Avoidability of major surgery	-327 864	9/22	-	19/22	-1 272	-	-2 643
Total cost	320 133				8 633	14 189	760
Cost per patient					157	258	14

As this evaluation was made from a TPP point of view, it could have been desirable to estimate indirect costs such as the cost of incapacity and reduced productivity; however, this was beyond the scope of the present study.

This study showed that the new procedure was more cost-effective (at SOAT tariffs) than the standard procedure for studying reproductive aged females suffering from non-specific abdominal pain from the TPP point of

view in 4 out of 5 scenarios. This study thus provides useful information for decision-makers for helping to implement new programmes ►

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