COST-EFFECTIVENESS COMPARISON OF TENSION-FREE MESH REPAIR VS. TENSION SUTURE REPAIR METHODS OF INGUINAL HERNIA IN MEXICO

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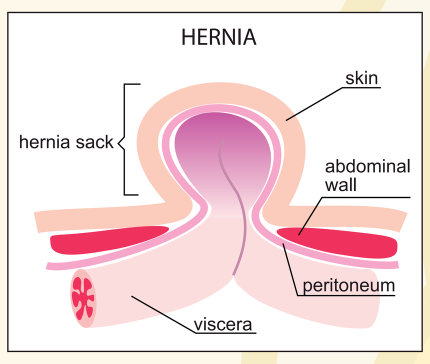
BACKGROUND

The purpose of this analysis is to provide healthcare providers, purchasers and surgeons with information that will enable them to better understand the clinical and health economic value of using meshes for the repair of inguinal hernia. This implantable medical device is designed to treat patients with inguinal hernia.

One of the milestones in the long history of hernia treatment was the implementation of meshes, which markedly increased the effectiveness ratios of herniorrhaphy. Current advances of surgical hernia treatment rely mainly on the progress in mesh materials and the development of a minimally invasive approach, such as laparoscopy.

Meshes are indicated for use in patients with inguinal hernias, according to the surgeon's decision. It is intended to be used during laparoscopic and open procedures, performed more and more frequently around the world. These types of treatments are currently used as first-line as well as second-line treatment of hernias, and the number of procedures is increasing each year.



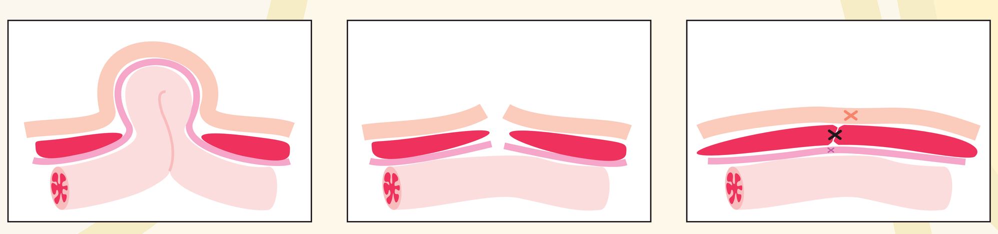
It seems to be a safe and effective method of abdominal wall hernia treatment, with a low complication rate, that may be placed by both a laparoscopic and an open approach, which is currently regarded as the gold standard of inguinal hernia repair.

It is assumed that overall recurrence after hernia repair amounts from 0.2 to 10% (Campanelli, Pettinari et al, 2006). The recurrence rate is, as mentioned above, strongly connected with the type of surgical intervention. According to published data, the recurrence rate of pure tissue repair (open non-mesh) performed in non-specialized centers may amount up to 35% (Amid, 2005).

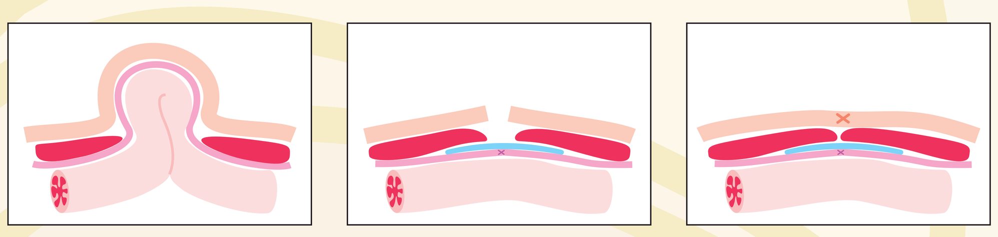
Development of new tension-free methods, performed conventionally or using a laparoscopic technique, tend to decrease the recurrence rate to 0.6 to 8% (laparoscopic) and 0 to 3.8% (open) (Arregui and Young, 2005). Tension - free techniques allow also decreasing the rate of other minor and major complications, especially in highly specialized centers (Arregui and Young, 2005).

Compared options

Open non-mesh



Open mesh



A large number of comparative trials revealed that mesh repair is more efficient and safe then open non-mesh repair, and the mesh implantation in front of the transversalis fascia is equally effective or even superior than open or laparoscopic implantation of mesh behind the transversalis fascia (Amid, 2005).

COST ANALYSIS FROM HEALTH CARE PROVIDER PERSPECTIVE

Methodology of the cost analysis from the service provider's perspective

Information on resource utilization and costs was collected on the basis of a study that was carried out in the Mexican Social Security Institute (IMSS), the General National Hospital La Raza Medical Center, (D.F.) and in the General Regional Hospital No. 36 San Alejandro (Puebla). The study was conducted between the April 1 and May 30, 2008.

Study participants were affiliates (insured working population and their families), adults at least 18 years of age with diagnosis of inguinal hernia. The surgery procedure was an elective treatment. Costs were obtained for different surgical techniques (open mesh –OM– and open non-mesh –ONM–). Five (5) patients were considered for each surgical procedure. Participants were carefully observed throughout their entire hospitalization period, which included the admission to the hospital and the operating room, the surgery itself, the recovery time at the postoperative ward (3-4 hours) and the final twenty four (24) hours at the general care ward.

The analysis was performed using IMSS's 2007 costs (Cost Database, Federal Department of Provision, IMSS).

The original study provided sufficient data to carry out the cost analysis. The data included the following cost categories:

- Direct medical costs:
  - Diagnostic tests,
  - Hospitalization,
  - Ambulatory attention,
  - Nursing,
  - Pharmacological treatment,
  - Specialist consultation.
- Direct non-medical costs:
  - Patient's transport,
  - Special diet,
  - Housing rearrangement,
  - Material loss as a result of patient's indisposition.
- Indirect medical costs:
  - Secondary effects: increase of survival, associated conditions.
- Indirect non-medical costs:
  - Loss of production due to indisposition or death,
  - Decrease in production,
  - Change of working place,
  - Loss of promotion opportunity,
  - Vulnerability to crime, imprisonment, criminal activity.

The above mentioned cost categories were transformed into new cost categories, as follows:

- Capital costs, which include estate (surgery in the operative block, cost of recovery in the postoperative ward), furniture, personnel taking part in the operation (surgeon, surgical technologist, anesthesiologist, anesthesiological nurse, ward attendant),
- Various indirect costs, such as human resources (non-medical personnel), maintenance, services, consumption,
- Various direct costs, including human resources, material used during therapy, pharmacotherapy, laboratory, radiology.

On the basis of obtained data, an average cost for each category was estimated. The average values from each sub-category were added in order to define aggregated costs, thus allowing a total cost estimate for all methods of hernia repairs. All costs are expressed as 2008 Mexican pesos (MXN).

Results – hospital perspective

Cost analysis from the IMSS's perspective outlines a significant cost difference between open non-mesh (tension) and open mesh (tension free) techniques for inguinal hernia repair. Lower costs are generated by mesh (tension-free) hernia repair method.

Table 1.
Total hernia repair costs borne by the IMSS (incl. operation costs and follow-up treatment)

Procedure name	Cost of surgical procedure	Cost of recovery	Total cost of the treatment (surgery + recovery)
Non mesh (tension) hernia repair	3,598.08	1,034.41	4,632.48
Mesh (tension free) hernia repair	2,950.57	1,307.35	4,257.92
Mean difference	647.51	-272.94	374.57

COST-EFFECTIVENESS COMPARISON OF SURGICAL TREATMENTS

Results of cost effectiveness analysis conducted in Mexico

One of the possible applications of Markov processes are Markov models, which are commonly used in economic evaluation of health care. To build these models, certain data is needed, such as the disease's mutually-exlusive health states, transition probabilities between these states and a predetermined cycle length.

The states of the disease (Markov states) are well defined clinical stages the patient could transit to, part from or stay at after each cycle (Markov cycles). An important assumption states that a patient must be in one disease state at one particular moment of time. Each one of the Markov states represent different heath status, different costs (which are incurred by the patients in the current state), utility levels (QoL) or other parameters of interest.

Transitions between Markov states indicate how patients can move between them within a given cycle. Transitions represent the natural course of disease, i.e., after every cycle the patient can transit to the following state, can stay in the same state or may die. As well, each and every state must be connected with the death state (death is a special kind of state, where once a patient reaches it he can not leave it, hence called an absorbing state).

Probabilities of a patient moving between one state and another within a cycle are presented in a transition probability matrix. The rows of this matrix represent transition probabilities from one state to the others The sum of probabilities in each row must add one (100%).

There are several ways of calculating results in Markov models. In our analysis we are using an analysis called second order Markov model simulation. It is based on the creation of a hypothetical cohort (group) of patients in the starting state and the further observation of its dynamics for a specific number of cycles. Patients move through the Markov states according to the probabilities defined in the transition probability matrix. In each cycle costs and utilities are estimated by multiplying the number of patients in each state by the cost of staying (cumulated utilities respectively) in it for one cycle.

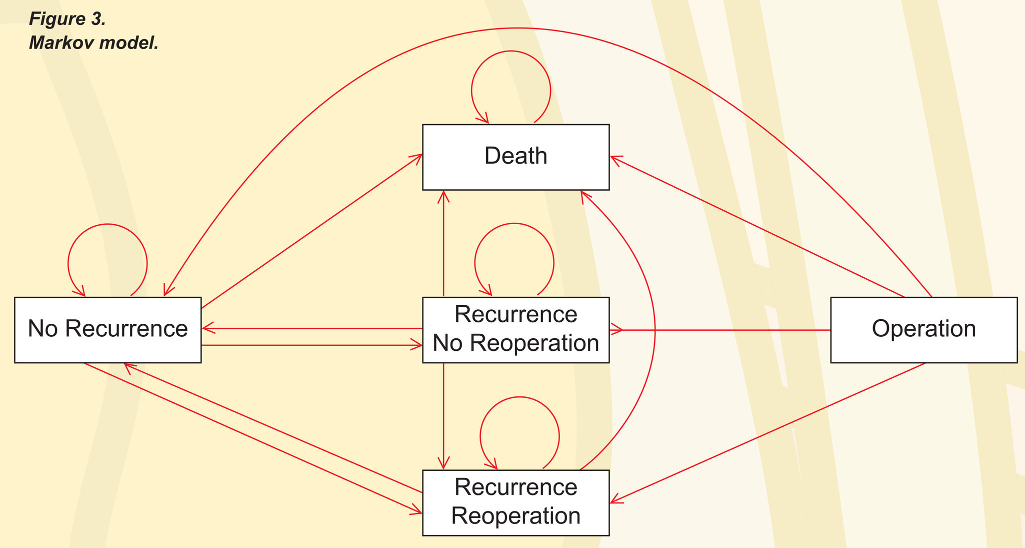
When performing probabilistic sensitivity analysis, input variables are taken from known probability distributions and randomly assigned during each and every iteration. This process is repeated several times, each iteration using a new transition probability matrix , costs and utilities, which are generated according to their respective probability distributions. The repetition of the simulation is performed to estimate confidence intervals as outcomes.

Disease states used in the present hernia Markov model are:

- Operation – this state takes into consideration all patients with inguinal hernia who agreed to surgical hernia repair; it also considers at least three (3) months of reconvalescence after surgery.
- Recurrence No Re-operation – this state takes into consideration all patients who experienced hernia recurrence during the cycle and did not agree to another surgical hernia repair.
- Recurrence Re-operation – this state takes into consideration all patients who suffer hernia recurrence during the cycle and agreed to reoperate it also considers reconvalescence three (3) months period after surgery.
- No Recurrence – this state takes into consideration all healthy patients after successful repair of inguinal hernia,
- Death – the absorbing state; this state takes into consideration patients who die from all causes considered in the model.

Notice that these clearly defined states are mutually exclusive.

Figure 3.
Markov model.



RESULTS - MEXICO

Table 3.
Markov model results in Mexico

				Cost	QALY/RA	ICER	Cost	QALY/RA	ICER
				Deterministic			Probabilistic		
IMSS									
Mexico	QALY	5	ONM	MXN 5,161.64	4.24	-MXN 125,033.67	MXN 5,074.17	4.23	-MXN 91,222.76
			OM	MXN 4,479.86	4.25		MXN 4,609.16	4.24	
		15	ONM	MXN 5,976.35	10.01	-MXN 63,616.88	MXN 5,850.01	9.99	-MXN 52,171.94
			OM	MXN 4,892.57	10.03		MXN 5,010.87	10.01	
	RA	5	ONM	MXN 5,161.64	0.85	-MXN 8,130.74	MXN 5,074.17	0.85	-MXN 5,829.47
			OM	MXN 4,479.86	0.93		MXN 4,609.16	0.93	
		15	ONM	MXN 5,976.35	0.54	-MXN 5,099.00	MXN 5,850.01	0.55	-MXN 4,119.46
			OM	MXN 4,892.57	0.75		MXN 5,010.87	0.75	

RA – recurrences avoided; QALY – Quality Adjusted Life Years; OM – open mesh; ONM – open non-mesh; ICER – Incremental Cost Effectiveness Ratio

IMSS

Figure 4.
CEAC 5 year QALY Mexico – IMSS perspective [MXN].

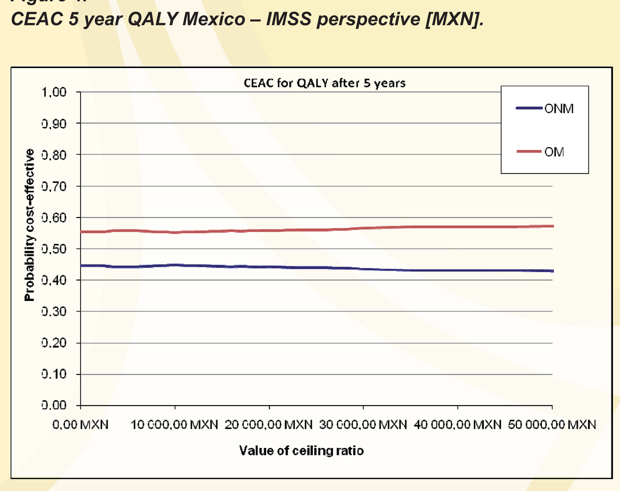
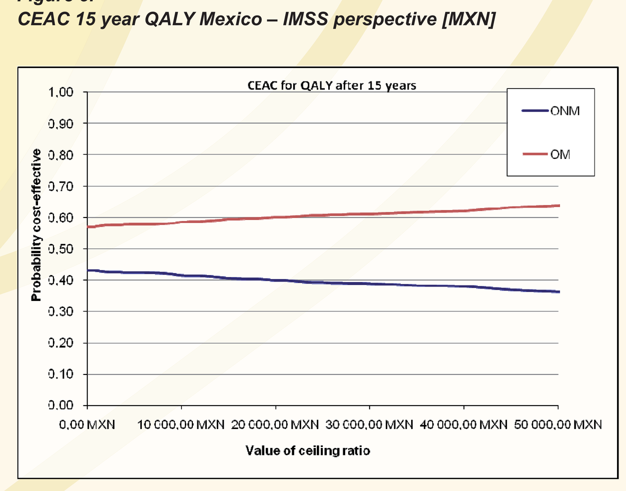


Figure 5.
CEAC 15 year QALY Mexico – IMSS perspective [MXN]



Conclusion from cost effectiveness analysis conducted in Mexico

Over a five (5) and fifteen (15) year period, the open mesh method dominates the open non-mesh technique, providing greater benefits in terms of more QALYs and fewer recurrences at a lower cost.

Findings suggest open mesh hernia repair method is a very cost effective therapy from a hospital's perspective for the inguinal hernia treatment in Mexico.

SUMMARY

Objective

The objective of this study was to compare the cost-effectiveness of open mesh vs. open non-mesh inguinal hernia repair in Mexico from a hospital's perspective.

Methods

Cost-effectiveness of open mesh vs. open non-mesh repair was modeled using a Markov model which evaluated a simulated cohort for a time horizon of up to 15 years. Model simulations were run in yearly cycles up to 15 years. Transition probabilities were derived from a systematic review and other published sources. Resource utilization data were collected from hospitals in Mexico. Utility values were extracted from published sources. Both costs and outcomes were discounted annually at 5%. Probabilistic sensitivity analysis simulations were repeated 10,000 times and CEAC curves were generated.

Results

Over both a five and fifteen year period, open mesh repair provides greater benefits in terms QALYs (0.0172 in favor of mesh in 15 years) and fewer recurrences than open non-mesh. When the costs from a payer's perspective were used, the open mesh repair was the dominant technology over open non-mesh repair. The cost in the open non mesh group was MXN 5161.56 in the 5 year horizon and MXN 5975.18 in the 15-year horizon. The cost in the open mesh group was MXN 4479.82 in a 5 year time frame and MXN 4891.61 in the 15 year horizon. Results of the probabilistic sensitivity analysis were robust and similar to deterministic analysis.

Conclusion

Findings suggest that in Mexico open mesh inguinal hernia repair is very cost effective from a hospital's perspective and should be considered the standard of care based on superior outcomes and lower costs.

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