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

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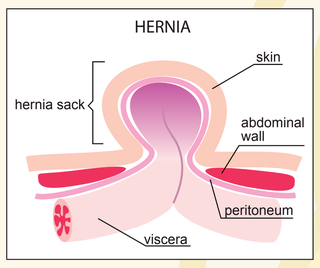
BACKGROUND

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 long history of hernia treatment was the implementation of meshes, that markedly increased the effectiveness ratios of herniorrhaphy. Current advances of surgical hernia treatment rely mainly on the progress in meshes materials and development of mini-invasive approach, such as laparoscopy.

This mesh is indicated for use in patients with groin 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 treatment are currently used as a first-line as well as the second-line treatment of hernias, and the number of procedures is increasing each year.



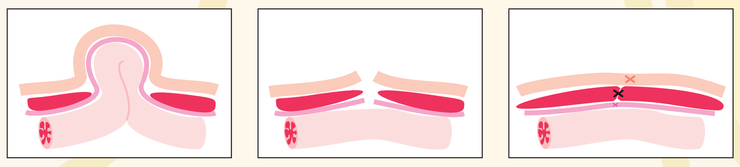
It seems to be a safe and effective method of abdominal wall hernia treatment, with low complications rate that may be used instead as a laparoscopic as well as open-mesh hernia repair, which is currently regarded as a "gold standard" of groin repair.

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 it was mentioned above, strongly connected with the type of surgical interventions. Accordingly to the data from literature, the recurrence rate of pure tissue repair (open non-mesh) performed in non-specialized centers may amount up to 35% (Amid 2005).

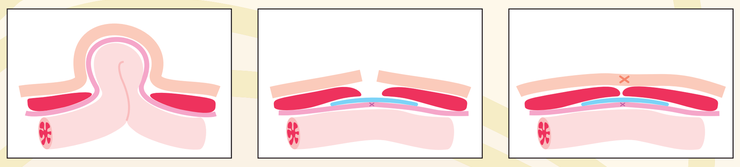
Development of new, tension-free methods performed conventionally or using a laparoscopic technique tend to decrease the recurrence rate to 0.6 to 8% (laparoscopic) and 0 to 3,8% (open) (Arregui and Young 2005). Tension - free techniques allow also decreasing the rate of other minor and major complications, especially in the highly specialized centers (Arregui and Young 2005).

Compared options

Open non-mesh



Open mesh



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 PAYER AND HEALTH CARE PROVIDER PERSPECTIVE

Methodology of the cost analysis from the SUS perspective

Information on cost of hernia repair procedures was identified on the basis of SUS reimbursement level refereeing to code 43.08.012-0 of Brazilian Medical Association Table 92 and 96.

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

Information on resource use and cost was requested from two service providers (private hospitals). The cost data for the analysis originate from administrative/financial and billing departments. Costs received as a result of prices analysis of products/services using retrospective data collection from other invoices, according to the demand or according to the payments made by health insurance companies, contracts, packages or the institution needs.

As addition for evaluation and better preparation for the explanations required during the analysis of the hospital invoices costs data about purchases, negotiations with the suppliers and audit, including "in loco" audits by the HIC were taken in to consideration.

On basis of data obtained from the providers and average cost of each hernia repair methods were calculated.

Results – SUS perspective

Cost analysis from the payer's perspective is a comprehensive view at the costs borne by the payer. It comprises not only financial resources spent for a procedure, but also the costs of specialist consultations in preoperative and post-operative period. The total cost of hernia repair borne by the payer is shown below:

Table 1.
Total hernia repair costs borne by the payer in 2007 (incl. operation costs and follow-up treatment)

Position	Open non mesh	Open mesh
Total hernia repair cost for SUS	R$ 372.44	R$ 507.44

Cost analysis from the SUS's perspective points out that there is a significant cost difference between non-mesh tension and mesh tension free method of hernia repair. Lower costs are generated by non-mesh tension hernia repair. However, it should be added that the cost difference is made mainly by the cost of mesh.

Results – hospital perspective

Lower costs accounted to R$ 470.49 are generated by non-mesh tension hernia repair. More expensive procedure is mesh tension free hernia repair which costs R$ 583.55.

Table 2.
Total costs from the service provider's perspective in 2007

No.	Cost Category	OM	ONM
1	Cost of stay in hospital		
1.1	Cost of hospital day	R$ 78.50	R$ 78.50
2	Procedure cost		
2.1	Surgical room and private hospital rzoom	R$ 88.77	R$ 104.67
2.2	Surgical room and private hospital room drugs	R$ 25.87	R$ 25.72
2.3	Surgeon's Fee	R$ 152.00	R$ 152.00
2.4	Assistant Surgeon's Fee	R$ 45.60	R$ 45.60
2.5	Anesthesiologist Fee	R$ 47.50	R$ 47.50
2.6	Oxygen	R$ 10.33	R$ 16.50
2.7	1Mesh	R$ 135.00	R$ -
	Total diversifying costs	R$ 583,55	R$ 470.49

COST-EFFECTIVENESS COMPARISON OF SURGICAL TREATMENTS

Results of cost effectiveness analysis conducted in Brazil

Markov Model used in economic evaluation is one of possible applications of Markov Process. Model is build with diseases states, possible transitions between these states and probabilities of these transitions within a given time period (a cycle).

Diseases state is an exact defined state of patient. There is an assumption that patient in one particular moment has to be in exact one disease state. Mainly Markov states have to represent different states of patient according to heath status, costs of being in that state, level of utilities like QoL or other parameters of interest.

Transitions between diseases states indicates how patients can move between them within a given period (a cycle). Transitions should represent natural course of disease, for example in every cycle patient can die, in the model each other state must be connected with death state (death is a special kind of state, which patient who reach it couldn't leave so it's called as an absorbing state).

Probabilities of a patient moving between one state and another within a cycle are presented in transition probability matrix. Rows of this matrix represent transition probabilities from one state to others, in consequence sum of probabilities in each row have to be one (100%).

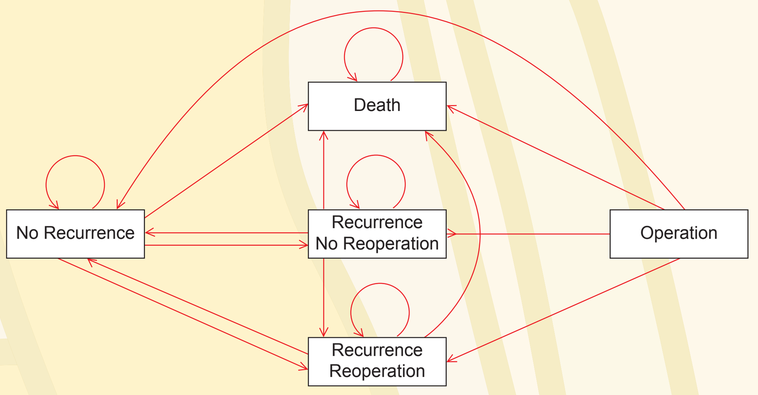
There are several types of calculating results in Markov model. In our analysis we are using an analysis called 2nd order Markov Model simulation. It's based on putting a cohort (group) of patient in starting state and observing those cohort for specific amount of cycles. Patients move through the model between states with the probabilities defined in transition probability matrix. In each cycle we are calculating costs and utilities for whole cohort by multiplying the number of patients in each state by the cost of staying (cumulated utilities respectively) in it for one period (a cycle). This process is repeated 1000 times, each time the new matrix of probabilities, costs and utilities is generated according to respective distributions. Repentance of simulation is performed to receive confidence intervals for results.

Disease states used in Hernia's Markov Model are:

- Operation – this state takes in to consideration all patients with inguinal hernia who agreed for surgical hernia repair, it also covers at least 3 months of reconvalescence after surgery,
- Recurrence No Re-operation – this state takes in to consideration all patients who's experienced a hernia recurrence during the cycle and doesn't agree for the next surgical hernia repair,
- Recurrence Re-operation – this state takes in to consideration all patients who suffer from a hernia recurrence during the cycle and agreed for it's re-operation, it also takes in to consideration reconvalescence 3 months period after surgery,
- No Recurrence – this state takes in to consideration all healthy patients after successful repair of inguinal hernia,
- Death – absorbing state, this state takes in to consideration only death patients from all causes.

Notice that those defined states are complementing one another to all possible patient state and also each two of states are disjunctive.

Figure 1.
Markov Model



SUMMARY

Objective

The objective of this study was to compare the cost-effectiveness of open mesh versus open non mesh inguinal hernia repair in Brazil from private hospital and private payer perspectives.

Methods

Cost-effectiveness of open mesh vs open non mesh repair was modeled using a Markov model. Model was evaluated as a cohort simulation for a time horizon up to 15 years. Transition probabilities were derived from systematic review and other published sources. Resource utilization data were collected from two private hospitals and a private payer in Brazil. Utility values were extracted from published sources. Both costs and outcomes were discounted annually at 5%. In probabilistic sensitive analysis simulations were repeated 10000 times. CEAC curves were generated as a result of simulation for all scenarios.

Results

Over both a five and fifteen year period, open mesh repair provides greater benefits in terms QALYs and fewer recurrences at a cumulatively higher cost than open non mesh repair procedures. Over a 5 and 15-year time frame, cost per one additional QALY is R$17,843 and R$2,991 respectively from a payer perspective and R$12,825 and R$957 respectively from a hospital perspective. Similarly, the cost per one recurrence avoided is 1162 R$ and R$245 in a five and fifteen years time horizon from payer perspective (R$836 and R$79 respectively from a hospital perspective). Results in the probabilistic sensitivity analysis were similar to deterministic analysis. In the five year perspective open mesh repair is more cost effective in comparison to open non mesh repair when the value for society's willingness to pay threshold for a QALY exceeds R$8000 for a life year (Zero R$ in the 15 years in both perspectives).

Conclusion

Findings suggest that in Brazil, open mesh inguinal hernia repair is cost effective from both private hospitals and private payer perspectives and should be considered standard of care based on superior outcomes and costs.

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RESULTS - BRAZIL

Table 3.
Markov model results in Brazil

				Cost	QALY/RA	ICER	Cost	QALY/RA	ICER
				Deterministic			Probabilistic		
SUS									
Brazil	QALY	5	ONM	R$ 436.69	4.2269	R$ 17,848.05	R$ 453.71	4.2178	R$ 18,475.72
			OM	R$ 533.70	4.2324		R$ 554.14	4.2233	
		15	ONM	R$ 531.01	9.8773	R$ 3,008.34	R$ 549.36	9.8555	R$ 961.89
			OM	R$ 581.54	9.8941		R$ 603.62	9.8718	
	RA	5	ONM	R$ 436.69	0.8410	R$ 1,162.81	R$ 453.71	0.8449	R$ 1,275.77
			OM	R$ 533.70	0.9244		R$ 554.14	0.9236	
		15	ONM	R$ 531.01	0.5234	R$ 245.16	R$ 549.36	0.5323	R$ 276.91
			OM	R$ 581.54	0.7296		R$ 603.62	0.7282	
Health Service Provider (private hospital)									
Brazil	QALY	5	ONM	R$ 544.05	4.2269	R$ 12,827.97	R$ 559.54	4.2171	R$ 13,279.16
			OM	R$ 613.77	4.2324		R$ 626.12	4.2222	
		15	ONM	R$ 652.75	9.8773	R$ 960.91	R$ 666.47	9.8536	R$ 961.89
			OM	R$ 668.89	9.8941		R$ 681.63	9.8694	
	RA	5	ONM	R$ 544.05	0.8410	R$ 835.75	R$ 559.54	0.8446	R$ 836.80
			OM	R$ 613.77	0.9244		R$ 626.12	0.9242	
		15	ONM	R$ 652.75	0.5234	R$ 78.31	R$ 666.47	0.5316	R$ 76.53
			OM	R$ 668.89	0.7296		R$ 681.63	0.7296	

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

Payer

Figure 2.
CEAC 5 year QALY Brazil – SUS perspective

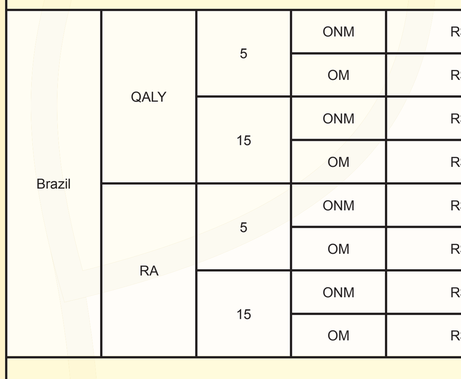
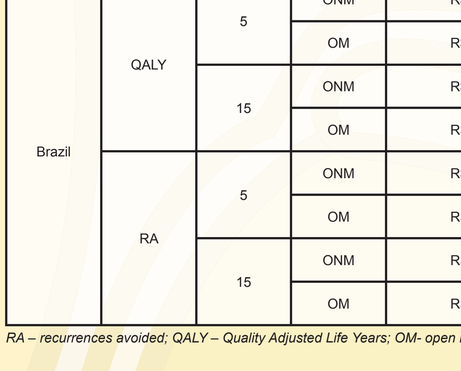


Figure 3.
CEAC 15 year QALY Brazil – SUS perspective



Hospital

Figure 4.
CEAC 5 year QALY Brazil – Hospital perspective

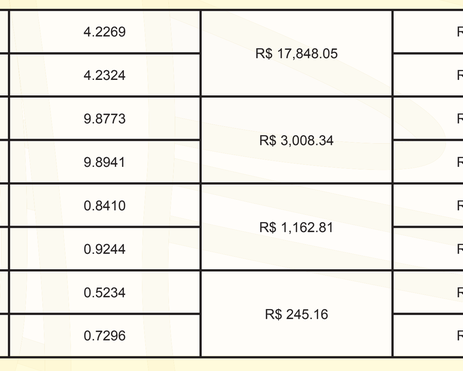
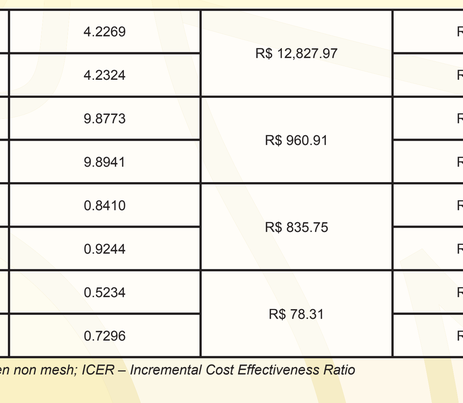


Figure 5.
CEAC 15 year QALY Brazil – Hospital perspective



Conclusion from cost effectiveness analysis conducted in Brazil

Over a five and fifteen year period open mesh provides greater benefits in terms of more QALYs and fewer recurrences at a cumulatively higher cost than open non mesh. The cost per one additional QALY is R$ 17,848.05 in a five years time horizon and R$ 3,008.34 in a fifteen years time horizon from a SUS perspective (R$ 12,827 and R$ 960 respectively from a hospital perspective). Cost per one recurrence avoided is R$ 1,162.81 in a five years time horizon and R$ 245.16 in a fifteen years time horizon from a SUS perspective (R$ 835.75 and R$ 78.31 respectively from hospital perspective). Results from the probability sensitivity analysis are very similar to deterministic analyses. In the five year perspective open mesh is more cost effective in comparison to the open non mesh option when the value for society's willingness to pay for a QALY exceeds R$ 14,000 (R$ 2,500 in the fifteen years perspective).

Findings suggest open mesh hernia repair method as a very cost effective therapy from both perspectives for the inguinal hernia treatment in Brazil.

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